Programmatic Environmental Assessment for the Manufacture and Use of aflasafe™ in Sub-Saharan Africa

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Cover photo: Corn infected with *Aspergillus flavus* in Babati, Tanzania. Credit: [redacted].

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LIST OF ACRONYMS

AATF	African Agricultural Technology Foundation
APPEAR	[USAID Project] Aflatoxin Policy and Program for the East Africa Region
ARS	[U.S. Department of Agriculture] Agricultural Research Service
AU	African Union
A/COR	Agreement/Contracting Officer's Representative
BEO	[USAID] Bureau Environmental Officer
CAADP	Comprehensive Africa Agriculture Development Programme
COMESA	Common Market for Eastern and Southern Africa
DNA	Deoxyribonucleic acid
EAC	East African Community
ECOWAS	Economic Community of West African States
EMMF	Environmental Mitigation and Monitoring Framework
EMMP	Environmental Mitigation and Monitoring Plan
EU	European Union
GMO	Genetically Modified Organism
GMP	[agricultural] good management practices
IEE	Initial Environmental Examination
IP	Implementing Partner
IITA	International Institute of Tropical Agriculture
MEO	Mission Environmental Officer
PACA	Partnership for Aflatoxin Control in Africa
PEA	Programmatic Environmental Assessment
ppb	parts per billion
PPE	personal protective equipment
QA/QC	quality assurance/quality control
REA/REO	Regional Environmental Adviser/Regional Environmental Officer
REC	[African Union] Regional Economic Commission or Regional Economic Communities
REGI	[USAID/East Africa Office of] Regional Economic Growth and Integration
SADC	Southern African Development Community
SOW	statement/scope of work
USEPA	U.S. Environmental Protection Agency
USAID	U.S. Agency for International Development

USAID/AFR	[USAID] Bureau for Africa
USAID/EA	USAID/East Africa [Regional Mission]
USDA	U.S. Department of Agriculture

EXECUTIVE SUMMARY

The fungus *Aspergillus flavus* (*A. flavus*) occurs naturally across large portions of sub-Saharan Africa (and in many other parts of the world). The fungus normally feeds on dead organic matter but may also infest cultivated crops such as maize and groundnuts. Crops infested with *A. flavus* present a substantial risk to food security and public health, as many strains of *A. flavus* are responsible for the production of aflatoxins. Aflatoxins are known to suppress immune response in mammals and are probable carcinogens. Crops infested with *A. flavus* are likely to manifest some level of aflatoxins, which will at minimum limit the crop's nutritional value to consumers. In extreme cases, contaminated crops may present an imminent threat to public health; accounts of aflatoxin poisoning outbreaks in sub-Saharan Africa are heard on a recurring basis, and deaths have been linked to the consumption of contaminated crops.

Concern over aflatoxins in sub-Saharan Africa has grown in recent years, with entities such as the Partnership for Aflatoxin Control in Africa (PACA) advocating for regional strategies and coordination to reverse negative effects on agricultural output and human health. USAID is an active participant in these efforts. Through projects like AflaSTOP and the Aflatoxin Policy and Program for the East Africa Region (APPEAR), USAID is supporting numerous initiatives to combat the prevalence and impact of aflatoxins. Many USAID-funded interventions focus on research, the strengthening of collaborative relationships, and the development and promotion of agricultural good management practices (GMPs) such as post-harvest handling and storage. Under the APPEAR project, however, USAID also seeks to support the commercialization of an aflatoxin bio-control product: aflasafe™.

The product aflasafe is based on a form of bio-control technology that has been used successfully in the United States for decades. It is predicated on competitive displacement, a process in which a 'safe' form of *A. flavus*—one that is incapable of producing aflatoxins—is introduced on fields that are vulnerable to contamination. The safe, or atoxigenic, forms of *A. flavus* that constitute aflasafe are allowed to establish and propagate among cultivated crops before the ambient, toxigenic forms of *A. flavus* can gain a foothold. This enables the atoxigenic fungus to dominate toxin-producing forms, substantially reducing the production of aflatoxins and leading to crops that are more valuable and healthier to consume. The development of aflasafe begins with the isolation of atoxigenic strains of *A. flavus*, which are the product of natural evolutionary mutations in the *A. flavus* genome (typically deletions in the aflatoxin-producing gene). While this process requires advanced laboratory-based sequencing and analysis, it does not represent transgenic or genetically modified organism (GMO) technology: all atoxigenic strains of *A. flavus* comprising aflasafe are naturally occurring.

The U.S. Environmental Protection Agency (USEPA) has registered two atoxigenic strains of *A. flavus* native to the United States as bio-pesticides for use on cotton and peanuts. Although this is an USEPA-approved form of bio-control, it is bounded by the use of atoxigenic strains of *A. flavus* indigenous to the United States (and not to Africa). Because aflasafe was developed for use in Africa, and necessarily integrates atoxigenic strains of *A. flavus* that are indigenous to Africa (and not the United States), USEPA registration status has not been extended to aflasafe, despite parity in the underlying technology.

It is in this context, consistent with USAID environmental procedures and compliance with U.S. federal law 22 CFR 216, that USAID undertakes this Programmatic Environmental Assessment (PEA) for the manufacture and use of aflasafe. This PEA is prepared under the direction of the USAID/East Africa Regional Mission in Nairobi, which is at the forefront of Agency programming to combat aflatoxins in the Africa region. The APPEAR project, under which aflasafe manufacture and use is currently proposed, is an East Africa regional initiative spanning several countries. The bio-control of aflatoxins has strong potential in other parts of Africa, as well, with aflasafe registration and farmer field trials in Nigeria and Senegal completed and underway, respectively. Researchers in Mozambique recently acquired the analytical laboratory instrumentation needed to begin strain identification, the first step in isolating the atoxigenic strains of *A.*

flavus needed to develop a locally appropriate form of aflasafe. USAID views the bio-control of aflatoxins—and more immediately the use of aflasafe—as an important programming option for advancing numerous development objectives across the Africa region. While USAID support for the manufacture and use of aflasafe may at present be unique to East Africa and the APPEAR project, it holds promise for a range of economic growth, food security and public health challenges. As such, this PEA is intended to address the potential adverse environmental impacts stemming from the manufacture and use of aflasafe as they may emerge across sub-Saharan Africa. Amendments to this "core" PEA may be prepared that will specifically address potential impacts at the country or sub-regional (e.g., West Africa, Southern Africa) level.

Preparation of this PEA followed a formal scoping process, which identified 10 "significant environmental issues" for more complete assessment. Two additional issues for assessment emerged following submission and review of the PEA Scoping Statement. The PEA team evaluated the 12 issues, which ranged from validity of the competitive displacement model to concerns over worker health and safety and the importance of marketing, through a combination of desk-based research, stakeholder interviews, and field work. Reflecting APPEAR project implementation, field work was completed in four East African countries (Kenya, Tanzania, Burundi and Uganda) in June 2014. Over the course of the assessment, the PEA team consulted with more than 50 stakeholders, a majority of which are Africa-based and directly involved in the development, testing, registration, manufacture, distribution, promotion, regulation, or use of aflasafe. The field work included visits to agricultural research stations, laboratories being equipped to support aflasafe production, and a prospective site for the construction of an aflasafe manufacturing facility. The team met with farmer groups and also consulted with agricultural input dealers and post-harvest processors. Additional research and a number of follow-up interviews were completed following return from the field to round out the team's assessment.

Through this process, the PEA team (see Attachment A) has concluded that aflasafe presents a unique and compelling opportunity for the control of aflatoxins in sub-Saharan Africa. The adoption of a proven, well exposed bio-control technology is likely to be one of the most effective approaches to limiting contamination on target crops. Concerns over the economic sustainability of aflasafe manufacture and use are vexing, however, and will require a balanced approach among proponents. Currently, there is tension between proponents of using aflasafe for the public good and those who see a need for commercial viability for aflasafe. For example, those emphasizing the public good aspect of aflasafe contend that aflasafe should be affordable for all farmers wishing to use the product. Conversely, those who focus on commercial viability argue that the best way to realize a benefit to public health is to make aflasafe an economically viable business venture. Despite this complexity, which carries only peripheral environmental risk, the benefits to public health and food security likely to be achieved through the use of this product are substantial.

At the same time, assessment of the potential adverse impacts associated with the manufacture, distribution and use of aflasafe indicates that a prudent approach to mitigation and monitoring can limit to an acceptable level any potentially harmful effects of aflasafe on human health and the environment. The PEA team further recommends that USAID support for aflasafe be linked to other aflatoxin control programs and strategies. Emerging technologies should also be considered as possible complements to aflasafe use. As awareness of aflatoxins increases in sub-Saharan Africa and USAID seeks to improve agricultural systems and public health in specific countries, the use of aflasafe should be viewed as a viable means of helping to meet these development objectives.

APPROVAL OF THE RECOMMENDED ENVIRONMENTAL ACTION FOR THE PROGRAMMATIC ENVIRONMENTAL ASSESSMENT FOR THE MANUFACTURE AND USE OF AFLASAFE™ IN SUB-SAHARAN AFRICA

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SECTION 1: INTRODUCTION

OVERVIEW OF AFLATOXIN AND AFLASAFE

Aflatoxins are potent toxins that are produced by certain strains of the fungus *Aspergillus flavus* (*A. flavus*)[1] which is predominantly a common saprophytic mold. Saprophytes obtain nutrients from dead organic matter. A *flavus* is common as a fungal infection on peanuts, grains,[2] and tree nuts, and it can adversely affect crop yield and pose serious risks to human health. Aflatoxins are known to suppress immune response in mammals and are probable carcinogens.[3] Not all strains of *A. flavus* produce aflatoxins. Those that do are termed "toxigenic" strains while those that do not are termed "atoxigenic."

aflasafe: an aflatoxin bio-control product trademark. Although the plant pathology and principles of pest control and crop protection used to develop this technology for sub-Saharan Africa may not be unique, the aflasafe name is. The product name aflasafe is a trademark for a particular form of aflatoxin bio-control, and will be referred to consistently throughout this PEA with a lower-case "a." The PEA's first in-text reference to aflasafe carries the superscript trademark symbol (™). Subsequent references are made without the trademark symbol, but with identical spelling.

A. flavus occurs naturally in many regions of the world, particularly in warmer climates. However, different strains of the fungus are indigenous to different regions. The U.S. Environmental Protection Agency (USEPA) has registered two atoxigenic strains of the fungus *A. flavus* as bio-pesticides to compete with strains of *A. flavus* that produce aflatoxins:

- *A. flavus* strain AF36, registered by USEPA in January 1991, for use on cotton fields in the states of Arizona and Texas,[4] and
- *A. flavus* strain NRRL 21882, registered by USEPA in May 2004, for use on peanuts.[5]

These USEPA-registered strains of *A. flavus* are not indigenous to Africa, however. The original version of aflasafe™ was a mixture of several naturally occurring—i.e., not genetically modified—atoxigenic strains of *A. flavus* indigenous to Nigeria;[6] hence, the specific strains comprising the active ingredient in aflasafe were not used in the United States, and were not registered by USEPA.

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1 Other fungi, such as *Aspergillus parasiticus* and *Aspergillus nomius*, have been identified as aflatoxin-producing; however *A. flavus* has been identified as the most common source of aflatoxins in West Africa. Donner, M., J. Atehnkeng, R.A. Sikora, R. Bandyopadhyay, and P.J. Cotty. 2010. Molecular characterization of atoxigenic strains for biological control of aflatoxins in Nigeria, *Food Additives and Contaminants*, Vol. 27, No. 5, May 2010, 576–590 (and references cited within). Available on the Internet at: http://www.aflasafe.com/c/document_library/get_file?p_l_id=524558&folderId=772842&name=DLFE-4683.pdf

2 Asao, T., G. Biichi, M.M. Abdel-Kader, S.B. Chang, E.L. Wick, and G.N. Wogan. 1965. The Structures of Aflatoxins B and G1. *Journal of the American Chemical Society*, 87:4, February 20, 1965, p. 882-886.

3 Cotty, P.J and K. Cardwell. 1999. Divergence of West African and North American Communities of Aspergillus Section Flavi, *Applied and Environmental Microbiology*, May 1999, p. 2264-2266 (and references cited within).

4 USEPA. 2003a. Biopesticides Fact Sheet for *Aspergillus flavus* strain AF36. USEPA. 2003b. Technical Document for Aspergillus flavus strain AF36 also referred to as a BRAD. Both Documents are available on the Internet at: http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:31:0::NO:1,3,31,7,12,25:P3_XCHEMICAL_ID:1268

5 USEPA. 2009. Biopesticides Fact Sheet for *Aspergillus flavus* strain NRRL 21882. USEPA. 2009b. Technical Document for Aspergillus flavus strain NRRL 21882 also referred to as a BRAD. Both Documents are available on the Internet at: http://iaspub.epa.gov/apex/pesticides/f?p=CHEMICALSEARCH:31:0::NO:1,3,31,7,12,25:P3_XCHEMICAL_ID:1269

6 The original "aflasafe™" is comprised of four atoxigenic strains of *A. flavus* of Nigerian origin. Other versions of aflasafe are being developed in other regions of Africa and will be identified with country- or region-specific suffixes using strains that are native to these other regions of Africa (e.g., aflasafe KE01 is being used in Kenya; http://r4dreview.org/2013/07/ensuring-the-safety-of-african-food-crops/). Most recently, the International Institute of Tropical Agriculture has been considering use of regional strains identified as being of East, West, and South African origin.

Although the strains that are registered by USEPA are different from those found in aflasafe, the bio-control technology associated with aflasafe is essentially identical to that associated with the strains registered by USEPA. The International Institute of Tropical Agriculture (IITA) holds a registered trademark on aflasafe (see text box on previous page).[7]

The theory behind aflasafe is that by promoting the growth of indigenous, atoxigenic strains of *A. flavus*, the toxigenic strains will be "out-competed," and the production of aflatoxins will therefore be greatly reduced. USAID is currently proposing to promote use of formulations of aflasafe that are native to East Africa to combat the toxigenic strains of *A. flavus* in East Africa. Eventually, use of other regionally specific strains of aflasafe may be used across all of sub-Saharan Africa. Efforts to identify natural strains of *A. flavus* in East Africa and other parts of sub-Saharan Africa are currently ongoing, and this identification phase is not subject to this Programmatic Environmental Assessment (PEA). In 2012, USAID prepared a review and evaluation of health effects associated with aflatoxins, agricultural measures to combat aflatoxins, and the effects of aflatoxins on trade. The report was intended to lay the groundwork in support of policy and program development and to highlight data gaps. The concept of "competitive displacement" is discussed in more detail in that report.[8]

FINDINGS FROM USAID ENVIRONMENTAL COMPLIANCE DOCUMENTATION

In East Africa, USAID support for aflasafe is currently planned for implementation under a USAID-supported program known as the Aflatoxin Policy and Program for the East Africa Region (APPEAR).[9] APPEAR puts into action the goals of the Partnership for Aflatoxin Control in Africa (PACA). PACA works in conjunction with the African Union (AU), Regional Economic Communities (RECs), member states, and the Comprehensive Africa Agricultural Development Program (CAADP) to foster improvements in food security, public health, and commerce in Africa through policy and program implementation.

USAID wishes to promote and support the use of aflasafe across sub-Saharan Africa. At present, however, it is the USAID East Africa Regional Mission (USAID/East Africa) in Nairobi that has been working with the East African Community (EAC) to advance PACA's policies and programs. Partnerships and technological advancements that are being realized in the EAC are therefore envisioned to serve as a model for all of sub-Saharan Africa. As such, this "core" PEA applies to USAID implementation of aflasafe activities throughout sub-Saharan Africa. PEA Amendments addressing aflasafe use at the sub-regional (i.e., West Africa, Southern Africa, etc.) or country levels will be prepared as necessary. Concurrent with preparation of this core PEA, a PEA Amendment addressing aflasafe use specifically in the East Africa region is being prepared. This methodology is discussed in additional detail in Section 5 of this document.

Implementation of the APPEAR project involves four primary elements: production of technical papers; capacity building; bio-control; and reports on progress. The use of aflasafe is encompassed by the bio-control element. A portfolio-level Initial Environmental Examination (IEE) and/or Request for Categorical Exclusion for USAID/East Africa/Regional Economic Growth and Integration (REGI), of which APPEAR is a part, was prepared and approved by the USAID Bureau Environmental Officer (BEO) in September 2011. While not referring specifically to the APPEAR project, the governing USAID/EA/REGI IEE does address approaches to aflatoxin control, under which the aflasafe work would fall: "Support to ongoing and

7 IITA. 2009. Maize farmers enjoy better grains with Aflasafe™, website. Available on the Internet at: http://old.iita.org/cms/details/print-article.aspx?articleid=3040&zoneid=81

8 USAID and Danya International, Inc. 2012. Aflatoxin: A Synthesis of the Research in Health, Agriculture, and Trade. Available on the Internet at: http://agrilinks.org/library/aflatoxin-synthesis-research-health-agriculture-and-trade

9 Aflatoxin Policy and Program for the East Africa Region (APPEAR) Statement of Work (SOW), February 2013; prepared by USAID.

new USAID programs in bio-fortification, aflatoxin control, dietary diversity and other topics linked to agriculture and trade, from which lessons can be learned and scaled up."[10] Since the governing IEE does not include a threshold decision for a Positive Determination, the need for this PEA is discussed in the APPEAR SOW.

The bio-control element of APPEAR is divided into two primary components (these are described in Section 2). The APPEAR SOW asserts that a Categorical Exclusion was granted by USAID for APPEAR activities that do not involve biophysical interventions (e.g., technical papers, capacity building, reporting of progress, and the regional, atoxigenic strain identification step of bio-control [i.e., Year One]). This PEA is therefore being prepared to cover the bio-control (i.e., the use of aflasafe) portion of the APPEAR project.

OUTCOMES FROM PEA SCOPING PROCESS

The PEA was initiated with a formal scoping process, as required by USAID environmental procedures. The resulting aflasafe PEA Scoping Statement identified 10 significant environmental issues for more complete assessment in this PEA. Note that these issues are not listed or ranked in terms of perceived significance or severity of potential adverse impact(s):

1. Toxigenic strains of *A. flavus* may contaminate aflasafe and compete for growth during formulation, manufacture, or use.
2. What effect might localized modular manufacturing locations have on sensitive subpopulations, such as those with compromised immune systems (either as workers involved in the manufacturing process or as nearby residents)?
3. The ability of aflasafe to effectively outcompete growth of other *Aspergillus* strains that may produce aflatoxins, such as *A. parasiticus* and *A. tamarii*.
4. Adherence by farmers and grain storage warehouse managers to all relevant good management practices (GMPs) to reduce risk of the growth of the toxigenic strains of *A. flavus* during aflasafe storage and use in the field.
5. Controlled manufacturing processes capable of producing adequate quantities of regionally specific formulations of aflasafe to maintain required application frequency to ensure long-term crop protection.
6. The potential for cessation of USAID funding and the potential for toxigenic strains to return with potentially greater toxicity and/or a perception of safe crops that are actually not safe.
7. Availability of robust sampling protocols and analytical methods to test for presence of aflatoxins in treated produce.
8. The potential for atoxigenic strains of *A. flavus* in aflasafe to become pathogenic through recombination processes in the environment.
9. The potential for aflasafe application to cause fungal infestation of crops which, while not toxic, may result in crops that are of limited or no nutritional value.
10. The scope of introducing aflasafe to the EAC and using the work in the EAC as a model for use of aflasafe across sub-Saharan Africa is such that issues may arise regarding consistency in proper procedural and implementation processes. Thus, a PEA is needed.

PEA METHODOLOGY

Preparation of this PEA involved four primary steps:

1. Work planning and field work preparations, including:

10 USAID. 2011. Initial Environmental Examination and Categorical Exclusion, Regional Economic Growth and Integration (REGI), East Africa.

   - Identification of key stakeholders and locations of interest for PEA field site visits, and scheduling meetings/site visits;
   - Collection of data to inform and support PEA field work.
2. Field work in Kenya, Tanzania, Burundi, and Uganda, including:
   - Meetings and interviews with key stakeholders;
   - Project visits to understand the modes in which aflasafe use will be promoted;
   - Site visits to technical facilities involved in the development and commercialization of aflasafe.
3. Desk work involving review of the scientific literature and interviews with stakeholders.
4. Synthesis of data from the scientific literature, interviews with stakeholders, and observations made in East Africa for use in the PEA.

The final draft PEA workplan is attached and provides detailed information on the planning process, field work itineraries, and research methodology.

In addition to the 10 significant environmental issues identified in the Scoping Statement, two additional questions/potential impacts were identified during the preparation of this PEA:

1. What effects might use of aflasafe have on termite mounds? Termites and certain fungi have a symbiotic relationship and there is concern that aflasafe may out-compete other species of fungi, such as those involved with termite populations.
2. What are the processes in place regarding marketing, certification, and/or distribution of products coming from aflasafe-treated fields?

SECTION 2: DESCRIPTION OF PROPOSED PROJECT/ACTIVITY

PURPOSE AND NEED FOR APPEAR BIO-CONTROL ACTIVITIES

Implemented by IITA, the APPEAR project is structured as a three-year effort touching on all phases of aflasafe technology development, from the identification of regional atoxigenic strains through the manufacture, field testing, and registration of aflasafe products in East Africa. USAID envisions that implementation of projects analogous to APPEAR could be used to further the use of aflasafe throughout sub-Saharan Africa. The general structure of APPEAR is as follows:

1. Year 1: Identification of atoxigenic, regional genotypes of *A. flavus* in East Africa. This work is related to work that has been performed and/or is ongoing as part of the development of aflasafe by IITA, in collaboration with the Agricultural Research Service (ARS) of the U.S. Department of Agriculture (USDA) and the African Agricultural Technology Foundation (AATF) in countries such as Nigeria and Kenya.
   This phase involves laboratory analysis that will be conducted by IITA, and is covered by the Categorical Exclusion granted by USAID in the governing IEE. Thus, the logistics of strain identification are not addressed in this PEA.
2. Years 2 and 3 ("Scale Up"): manufacture, field testing, and regional licensing of regional, atoxigenic strains of *A. flavus* in East Africa. The potential environmental, human health, sociological, and economic impacts of the manufacture and field testing are evaluated in this PEA.

While licensing/registration of the atoxigenic strains of *A. flavus* at the regional or country level may be an obstacle to the successful implementation of this project, the licensing/registration process itself is not anticipated to have adverse environmental, human health, sociological, or economic impacts. However, since licensing/registration of aflasafe is an integral part of the implementation of this work, country-specific procedures are presented in the relevant PEA Amendment(s).

INTENDED BENEFICIARIES

The developers of the aflasafe technology, along with IITA, envision the introduction of aflasafe to all countries in sub-Saharan Africa. Beneficiaries would range from:

- Smallholder farmers and their families—scenarios in which all of the treated maize would be used for personal consumption and/or sold at local markets (or aggregated for export) and/or used for domestic animals and aquatic life;
- Medium to large-scale farmers—scenarios where treated maize would be used for household consumption, as well as sold at local markets or for possible export;
- Commercial farmers—scenarios where the primary goal of cultivation is capital gain, either through local sale, export, or for use in the poultry industry (aflasafe has improved the quality of poultry feed in Africa, particularly in Nigeria).[11]

11 Personal communication with Kola Masha, Managing Partner, Doreo Partners; 2 July, 2014, via teleconference.

SECTION 3: BASELINE ENVIRONMENTAL DATA AND AFFECTED ENVIRONMENT

OVERVIEW OF AGRO-ECOLOGICAL ZONES OF SUB-SAHARAN AFRICA

In terms of land type, sub-Saharan Africa is located within the Afrotropic biogeographic realm and comprises mainly tropical and subtropical grasslands, savannas, and shrublands; tropical and subtropical moist broadleaf forests; montane grasslands and shrublands; and deserts and xeric shrublands.[12] East African climate comprises five agro-ecological zones, covering the following percent area of East Africa:[13]

- Arid zone—52 percent. This zone receives 0–500 mm of rainfall annually, and the growing season (i.e., the duration for which plant life can be sustained) generally lasts less than three months;
- Semi-arid zone—18 percent. This zone receives 500–1,000 mm of rainfall annually, and the growing season may be 3–6 months long;
- Sub-humid zone—16 percent. This zone receives 1,000–1,500 mm of rainfall annually, and the growing season may be 6–9 months long;
- Humid zone—2 percent. This zone receives >1,500 mm of rainfall annually, and the growing season may be 9–12 months long;
- Highland zone—12 percent. Highlands are located within the semi-arid, sub-humid, and humid zones, but the average daily temperature during the growing season(s) is <20°C.

OCCURRENCE OF *ASPERGILLUS FLAVUS* IN AFRICA

A. flavus is a common, naturally occurring fungus that is commonly found in soil across much of sub-Saharan Africa. Aflatoxin contamination (due to growth of the toxigenic strains of *A. flavus* and to the actual production of aflatoxins) in produce can occur if the crop is damaged by insects or stressed due to high-heat and/or low-precipitation environments. In addition, high heat and high humidity during crop storage or drying can promote aflatoxin contamination.[14] Two factors must be considered when translating the conditions that are favorable for the production of aflatoxins to the conditions that are favorable for growth of the atoxigenic strains of *A. flavus* found in aflasafe: 1) conditions favorable for the growth of *A. flavus* generally; and (2) conditions favorable for the production of aflatoxins by the toxigenic strains of *A. flavus*. Most data are available for conditions that favor *A. flavus* production (in an effort to design preventive measures), but the issue is confounded by which factors may favor the production of aflatoxins. In general, growth of *A. flavus* is favored by warm, dry conditions.[15]

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Bandyopadhyay, R. D. Akande, and P.J. Cotty. 2014. The Science of aflasafe and its Development for Aflatoxin Mitigation. Presentation at USAID Headquarters, Washington, DC. 21 March, 2014.

15 Atehnkeng, J., P.S. Ojiambo, M. Donner, T. Ikotun, R.A. Sikora, P.J. Cotty, and R. Bandyopadhyay. 2008. Distribution and toxigenicity of Aspergillus species isolated from maize kernels from three agro-ecological zones in Nigeria. *International Journal of Food Microbiology*, Vol 122, 74–84 (and references cited within).

A. flavus has been shown to be common in field tests performed in various agro-ecological zones in Nigeria and Benin. In Nigeria, *A. flavus* was identified as the most common fungus found on maize samples collected from three different agro-ecological zones,[16] while in Benin, *A. flavus* was found to be the most common fungus found in soil samples collected from agricultural areas in four different agro-ecological zones.[17] Note that while the focus of these studies was to characterize the toxigenic/atoxigenic nature of the fungi isolated (in the case of the Benin study), or the aflatoxin production of the fungi isolated (in the case of the Nigeria study), the occurrence and prevalence of *A. flavus* in these studies is evaluated here in relationship to the ecological conditions that favor growth of *A. flavus*, without regard to its ability to produce or not produce aflatoxins. This evaluation is summarized in Tables 1 and 2.

Table 1: Results of Nigeria Study Assessing Aflatoxin Production of Isolated Fungi

AGRO-ECOLOGICAL ZONE	LATITUDE	AVERAGE RAINFALL (MM)	TEMPERATURE (MAX)	% KERNELS INFECTED BY GENUS *ASPERGILLUS* (RANGE)	% KERNELS INFECTED BY GENUS *ASPERGILLUS* (MEAN)
Derived Savanna	6°8'-9°30' N	1,300-1,500	25-35°C	27-100%	70.4%
Southern Guinea Savanna	8°4'-11°3' N	1,000-1,300	26-38°C	41-100%	84.4%
Northern Guinea Savanna	9°10'-11°59' N	900-1,000	28-40°C	0-70%	14.0%

The authors report that, in these three regions, temperatures increase and precipitation decreases with increasing latitude. Thus, since higher temperature and dry conditions favor growth of *A. flavus*, the highest amounts of aflatoxins would be expected in the Northern Guinea Savanna. However, the authors found the highest amount of aflatoxin contamination in the Southern Guinea Savanna. The authors further indicate that aflatoxin contamination is dependent upon complex relationships among insects, fungi, maize genotype, and environmental conditions. Crop management practices also appear to play a role.

[16] Ibid.

[17] Cardwell, K.F. and P.J. Cotty. 2002. Distribution of Aspergillus Section Flavi among Field Soils from the Four Agroecological Zones of the Republic of Bénin, West Africa. *Plant Disease*, Vol. 86, No. 4, 434-439 (and references cited within).

Table 2: Results of Benin Study (1994-1996) Characterizing Toxigenic/Atoxigenic Nature of Isolated Fungi

AGRO-ECOLOGICAL ZONE	LATITUDE	AVERAGE RAINFALL (MM)	TEMPERATURE (MEAN OR MAX)	SOIL PH	% *A. FLAVUS*	COLONY-FORMING UNITS/G OF SOIL
Coastal Savanna	S of 7.5° N	1,300-1,500	25-35°C (mean)	6.9-7.8	92-100%	61-7,868
Southern Guinea Savanna	7.5°-8.5° N	1,000-1,300	26-38°C (max)	6.5-7.5	86-100%	15-320
Northern Guinea Savanna	8.5°-10.5° N	1,000-1,100	28-40°C (max)	5.7-7.2	71-100%	15-1,262
Sudan Savanna	10.5°-12.5° N	900-1,000	28-45°C (max)	6.5-7.2	40-100%	6-91

The authors report that, in these four regions, temperatures increase and precipitation decreases with increasing latitude. As with the study performed in Nigeria and discussed above, the highest amounts of aflatoxin contamination might be expected in the Sudan Savanna. However, while some sites in all four regions showed 100 percent *A. flavus* as the fungal type, the region with the largest number of observed colony-forming units per gram (CFU/g) was the Coastal Savanna. The authors indicate that climatic variability across the four regions presents a range of conditions where aflatoxin contamination may occur. As mentioned above, other ecological relationships play a role in growth of *A. flavus* and aflatoxin production.

Based on research on the observed production of aflatoxins, the regions in sub-Saharan Africa most amenable to the use of aflasafe—and that would also be suitable for farming—appear to be:

- Tropical and subtropical grasslands, savannas, and shrublands;
- Montane grasslands and shrublands;
- Xeric shrublands (which may be too arid for farming).

Climatically, the semi-arid zone and sub-humid zone seem to correlate best with the zones studied in West Africa and described above. The arid zone may present favorable environmental conditions for the growth of *A. flavus*, but it may not be suitable for successful farming. Climatic conditions in sub-Saharan Africa may also alter over time, due at least in part to the effects of global climate change. In a recent report commissioned by the World Bank,[18] the following changes are postulated to occur in sub-Saharan Africa based on a 4°C temperature rise by the end of this century:

- Increased probability of droughts in central and southern Africa;
- Increased annual precipitation in portions of East Africa and the Horn of Africa that are anticipated to occur with greater intensity (bursts), resulting in an increased risk of flooding;
- A shift from grasslands/savannahs to wooded savannas;
- Adverse impacts on agricultural crop production;
- An increase in the area classified as arid or hyper-arid for all of sub-Saharan Africa.

The potential effects of global climate change may differ substantially from sub-region to sub-region. It should also be noted that the World Bank report indicates that a significant amount of uncertainty exists over estimated changes in precipitation, particularly for East and West Africa.

18 World Bank. 2013. Turn Down the Heat: Climate Extremes, Regional Impacts, and the Case for Resilience. A report for the World Bank by the Potsdam Institute for Climate Impact Research and Climate Analytics. Washington, DC: World Bank. License: Creative Commons Attribution–Non-Commercial–No Derivatives 3.0 Unported license (CC BY-NC-ND 3.0). Available on the Internet at: http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2013/06/14/000445729_20130614145941/Rendered/PDF/784240WP0Full00D0CONF0to0June19090L.pdf

Additional country-specific data and discussion regarding agro-ecological zones for Kenya, Tanzania, Burundi, and Uganda are provided in the current PEA Amendment for USAID/East Africa. Additional Amendments to this PEA will address environmental conditions at the country level to help accurately inform the assessment of aflasafe manufacture and use in a particular geographic or programmatic context.

SECTION 4: POLICY, LEGAL, REGULATORY, AND INSTITUTIONAL SETTING FOR AFLASAFE MANUFACTURE AND USE

Effective and sustainable implementation of the proposed bio-control activities across sub-Saharan Africa will require USAID and its partners to coordinate with multiple regional and country-level institutions. USAID will also need to adhere to applicable regional and national regulations, particularly those that pertain to the manufacture, distribution, and use of agro-inputs, including bio-pesticides such as aflasafe. This type of coordination and integration will require USAID to navigate the matrix of regional and national jurisdictions through the various stages of project implementation. Through this process, USAID and its partners can work more effectively with the proper regional and host-country officials and within applicable regulatory framework(s).

REGIONAL POLICY AND INSTITUTIONAL SETTING

As previously discussed, the goals of the USAID APPEAR project align broadly with those of PACA, a continental initiative that promotes improved food security, public health, and commerce in Africa. PACA works in conjunction with the AU, RECs, member states, and the CAADP in the following five strategic areas:[19]

1. Generating and promoting research and technology for the promotion and control of aflatoxins
2. Developing policies, legislation, and standards for the management of aflatoxins
3. Growing commerce and trade and protecting human health from aflatoxins
4. Enhancing capacity for effective aflatoxin prevention and control
5. Increasing public awareness, advocacy, and communication

The CAADP is a central driver of economic growth and food security across sub-Saharan Africa and works primarily through the AU's New Partnership for Africa's Development (AU/NEPAD) agenda.[20] CAADP is charged with using agricultural development to reduce hunger and poverty, increase food security, and promote economic growth and increased trade.

Additionally, RECs serve as centers of regional economic integration and collaboration. In East Africa, active RECs include the Common Market for Eastern and Southern Africa (COMESA) and EAC. In West Africa, the Economic Community of West African States (ECOWAS) is the predominant REC, while the Southern African Development Community (SADC) and COMESA are the primary regional economic bodies in Southern Africa. Coordination of aflasafe-related activities with these regional bodies can draw upon—and can help foster—the harmonization of policies and practices designed to control aflatoxins. The most relevant of these regional policies and practices to bio-control efforts are likely to center on bio-pesticide registration criteria, sampling and testing protocols for aflatoxins, and sanitary and phyto-sanitary standards. Harmonization within, and potentially between, RECs has the potential to strengthen the development and use of aflasafe; the application of a high-quality bio-control product under uniform, high-quality standards will promote efficacy and safe use across countries. Regional support for aflasafe manufacture and use is also viewed as one means of enhancing agricultural export markets, as REC-level standards, systems, or protocols can provide a degree of assurance regarding the quality of exported goods.

[19] Partnership for Aflatoxin Control in Africa (PACA). 2014. Theme 2: Driving for enforceable policies, regulations, and standards to prevent and control aflatoxins. Available on the Internet at: http://www.aflatoxinpartnership.org/?q=theme-two

[20] Federal Ministry of Agriculture and Water Resources, Nigeria. 2009. Nigeria ECOWAP/CAADP Compact. Available on the Internet at: http://caadp.net/sites/default/files/documents/CAADP-Compacts/ECOWAS/Nigeria/Nigeria-Signed-Compact.pdf

HOST-COUNTRY POLICY AND INSTITUTIONAL SETTING

Each sovereign country in sub-Saharan Africa has a regulatory process that can be extended to the manufacture and use of aflasafe. This process may or may not align with neighboring countries' regulations, or with norms that may be observed across sub-Saharan Africa. Regardless of any differences that might exist between host-country regulation and any regional standards, host-country standards should be assumed to take precedence. Individual countries may seek to model or conform national regulations concerning aflasafe manufacture and use to regional standards. Certain countries may also wish to cede aspects of the bio-pesticide registration process to a regional body. However, this is the domain of the cognizant host-country institutions; these entities will need to reconcile host-country regulation with regional standards or processes.

In all instances, USAID support for the manufacture or use of aflasafe, a bio-pesticide, in an individual country is contingent on the registration (or formal approval) for use of aflasafe by the host country entity charged with pesticide regulation. This registration or approval process may or may not integrate a regional approach or methodology.

Countries that have adopted certain regional standards for aflasafe manufacture and use may also retain elements of bio-control regulation that are unique to the host country. These may reflect country-level considerations for which project implementers must properly account. As they are prepared, Amendments to this PEA will address pesticide registration processes at the country level.

The proposed bio-control activities will likely entail interaction with the following types of host-country institutional programs: pesticide registration and oversight, agricultural production, soil and water management, environmental protection, food safety, public health and health research, and trade promotion. Common names for the entities managing these programs in sub-Saharan Africa include ministry of agriculture (with departments such as food safety, food technology, and crop systems), pesticide board or pesticide research institute, ministry of environment, ministry of health, and the bureau of standards. Common names for relevant host-country laws and regulations include Law on Environmental Impact Assessment, Pesticide Registration Act, or Law on Pesticide Registration.

In addition to the regulatory bodies within each country, specific facilities and capacity must be considered and understood. Laboratory quality and capability are essential for evaluation of aflatoxin levels. Agricultural or pesticide research institutes develop and inform the technical capacity of country scientists. Local universities as well as government agencies are also important sources of technical capacity.

GLOBAL CONTEXT

The most urgent objectives of the proposed bio-control activities are to increase food security and improve public health among affected populations. As they do not directly involve international trade, these objectives do not require bio-control efforts to result in agricultural products that meet various international standards for aflatoxin contamination, such as those promulgated by theUnited States, European Union (EU), or China. In defining long-term objectives, however, the manufacture and use of aflasafe should reasonably be measured against broader food safety standards so that trade competitiveness can also be achieved once the more urgent food security and public health risk are addressed. Current international standards for total aflatoxins in the United States, EU, China, Nigeria, Kenya, and South Africa are summarized in Table 3 below: [21]

[21] Aflatoxin B1, B2, G1, and G2

Table 3: Current International Standard for Aflatoxin Contamination of Maize and Groundnuts

PRODUCT/STANDARD[22,23]	US	EU	CHINA	NIGERIA	KENYA	SOUTH AFRICA
Groundnuts	20 ppb	4 ppb, 15 ppb*	20 ppb	4 ppb, 15 ppb*	10 ppb	10 ppb
Maize	20 ppb	4 ppb, 10 ppb*	20 ppb	20 ppb		10 ppb

*Limit for product to be subjected to sorting, or other physical treatment, before human consumption or as ingredient in foodstuffs.

The variation in international standards for aflatoxins presents a general challenge as actors in sub-Saharan Africa seek to define regional and/or country-level benchmarks for food safety. While the fundamental objective of establishing regional and country-level standards is focused on the production and consumption of food that is safe, a secondary objective may be to bolster competitiveness in international trade.

[22] www.mycotoxins.info. 2014. Origin Matters – Mycotoxins Affect Everyone! Regulations for Feed, website. Available on the Internet at: http://www.mycotoxins.info/myco_info/stor_f_reg.html

[23] www.mycotoxins.info. 2014. Origin Matters – Mycotoxins Affect Everyone! Regulations for Food, website. Available on the Internet at: http://www.mycotoxins.info/myco_info/consum_regu.html

SECTION 5: ASSESSMENT OF THE POTENTIAL ENVIRONMENTAL IMPACTS (OR CONSEQUENCES) OF AFLASAFE MANUFACTURE AND USE.

Potential USAID support for the manufacture, distribution, and use of aflasafe—through implementation of the APPEAR project, or any similar program or initiative—carries the risk of potential adverse impacts on the environment. Because aflasafe is a bio-pesticide and will be used to treat crops that will be consumed by the farmers who grow the crops, or by people who purchase the crops, aflasafe also presents the risk of potential adverse impacts on human health. The PEA scoping process considered the full range of potential adverse impacts stemming from aflasafe manufacture and use, narrowing the list to 10 significant environmental issues. These issues are enumerated in Section 1 of this PEA and included below in Table 4.

In addition to the 10 issues identified in the PEA Scoping Statement, two additional issues emerged in consultations following USAID-internal discussion of the completed Scoping Statement, and the PEA work planning process. These issues complement those identified through the scoping process and are intended to broaden the PEA team's technical mandate to evaluate all reasonable sets of concerns or uncertainties. The two additional issues included for evaluation in the PEA are below:

1. What effects might use of aflasafe have on termite mounds? Termites and certain fungi have a symbiotic relationship and there is concern that aflasafe may out-compete other species of fungi, such as those involved with termite populations.
2. What are the processes in place regarding marketing, certification, and/or distribution of products coming from aflasafe-treated fields?

This section of the PEA discusses the 12 significant environmental issues associated with the manufacture and use of aflasafe and assesses their potential impact(s) on human health and the environment. The assessment qualifies potential impacts according to significance and establishes top-level environmental mitigation and monitoring criteria.

A more detailed presentation of mitigation and monitoring requirements is provided in Section 7, including specific actions that must be taken to reduce the incidence and/or severity of the potential adverse impacts identified below.

Table 4: Significant Environmental Issues Associated with the Manufacture and Use of aflasafe

NO.	DESCRIPTION OF SIGNIFICANT ENVIRONMENTAL ISSUE (AS DETERMINED IN AFLASAFE SCOPING STATEMENT)	DISCUSSION OF ISSUE AND ASSESSMENT OF SIGNIFICANCE
1	Toxigenic strains of *A. flavus* may contaminate aflasafe and compete for growth during formulation, manufacture, or use.	Toxigenic and atoxigenic strains of *A. flavus* have coexisted for millennia and the intermingling of different strains is a naturally occurring phenomenon, if at differing ratios. Nevertheless, the formulation and manufacturing processes will be completed using technologies and environmental controls meant to prevent the introduction of toxigenic strains into the product. Quality assurance (QA) is to be achieved through ongoing laboratory analysis that validates the integrity of aflasafe through the formulation and manufacturing processes.

NO.	DESCRIPTION OF SIGNIFICANT ENVIRONMENTAL ISSUE (AS DETERMINED IN AFLASAFE SCOPING STATEMENT)	DISCUSSION OF ISSUE AND ASSESSMENT OF SIGNIFICANCE
		Some contamination during product use is not unrealistic, but the prevalence of atoxigenic fungus will greatly outnumber toxigenic strains in areas where the product is being applied. Any contamination of the product by toxigenic strains during product use would have negligible adverse impacts as instances of contamination would not represent a higher incidence of toxigenic strains than are already present in the immediate environment.
2	What effect might localized modular manufacturing locations have on sensitive subpopulations, such as those with compromised immune systems (either as workers involved in the manufacturing process or as nearby residents)?	Any (bio) pesticide manufacturing facility will need to comply with basic worker safety and environmental controls, such as air handling equipment, and wastewater and solid waste management. Basic, low-cost facility and process controls and mitigation measures at the manufacturing phase can effectively contain aflasafe and its active ingredients, preventing dispersal or contamination of the local environment and potential adverse impacts on nearby sensitive or immunocompromised populations. Among workers, basic personal protective equipment (PPE) requirements should safeguard any particularly sensitive personnel from the health impacts most commonly associated with the handling of fungal agents by immunocompromised individuals, such as invasive aspergillosis and other pulmonary infections.[24] Specific manufacturing processes, such as those used by IITA, can also be implemented to reduce the risk to workers and nearby residents. (IITA minimizes the dispersal of spores in the manufacturing facility and within the environment in the area surrounding the manufacturing facility by treating the roasted sorghum seed substrate with a suspension of atoxigenic *A. flavus*, polymeric adherent, and dye in a commercial seed coater. In this way, the spores are contained within the adherent/dye suspension, minimizing dispersal of the spores.)[25] Individual host-country regulation may stipulate additional manufacturing controls and worker health and safety criteria that further reduce the risk presented by localized aflasafe production.
3	The ability of aflasafe to effectively outcompete growth of other *Aspergillus* strains that may produce aflatoxins, such as *A. parasiticus* and *A. tamarii*.	The product aflasafe is shown to be extremely effective in outcompeting other species of *Aspergillus*. This is primarily because of the nature and timing of aflasafe application, which provides a significant competitive advantage in the proliferation of atoxigenic strains. The product is deployed early, and above the soil matrix, enabling more rapid dissemination to surrounding crops. The roasted sorghum (or equivalent) substrate provides an immediate food source for the atoxigenic strains, allowing them to flourish and disperse before other strains would normally establish on nearby crops. This so-called "founder effect" allows aflasafe to

[24] Centers for Disease Control and Prevention (CDC). 2014. Fungal Diseases, Aspergillosis, website. Available on the Internet at: http://www.cdc.gov/fungal/diseases/aspergillosis/ Accessed online 11 July, 2014.

[25] Per comments on the draft PEA provided by Ranajit Bandhyopadhyay, IITA.

NO.	DESCRIPTION OF SIGNIFICANT ENVIRONMENTAL ISSUE (AS DETERMINED IN AFLASAFE SCOPING STATEMENT)	DISCUSSION OF ISSUE AND ASSESSMENT OF SIGNIFICANCE
		effectively displace (i.e., outcompete) toxin-producing forms of *Aspergillus*.
4	Adherence by farmers and grain storage warehouse managers to all relevant GMPs to reduce risk of growth of the toxigenic strains of *A. flavus* during aflasafe storage and use in the field.	As discussed above, the normal aflasafe production process should preclude contamination of the finished, packaged product with toxigenic strains of *A. flavus,* therefore limiting the growth of these strains prior to opening of the factory packaging. Numerous environmental controls and QA measures are needed to provide a high level of confidence that packaged aflasafe is free of any toxigenic strains. Normal aflasafe product packaging (e.g., poly bags or sealed plastic containers) should eliminate the risk of contamination with toxigenic strains of *A. flavus* during storage of unopened, unused products. By following basic instructions (in written or illustrated form), farmers and grain storage warehouse managers can retain the integrity of aflasafe for the duration of its two-year shelf life. Once the product is opened from its original packaging and/or applied in the field, some contamination and subsequent growth of toxigenic strains of *A. flavus* is possible. However, the prevalence of atoxigenic fungus will greatly outnumber toxigenic strains in areas where the product is being applied. Any contamination of the product by toxigenic strains during product use would have negligible adverse impacts as instances of contamination would not represent a higher incidence of toxigenic strains than already occurs in the immediate environment. The broader use of GMPs will remain a challenge among potential aflasafe consumers, particularly individual smallholder farmers. However, adherence to even modest GMPs will significantly limit post-production contamination. Common-sense storage practices should preclude growth of the toxigenic strains of *A. flavus* prior to product use (and unsealing of aflasafe packaging), while prescribed field application techniques in accordance with product labeling will likely lead to an acceptable level of growth during use. Although the use of GMPs is always a prudent action, the nature of aflasafe is such that, once it is deployed in the field, it will likely out-compete any toxigenic strains that may arise from poor storage practices, due to the preponderance of atoxigenic strains. One kilogram of sorghum seed carrier is coated with more than 20 million spores of atoxigenic strains. This high dose of atoxigenic strains will crowd out contaminants, including toxigenic strains, if the atoxigenic strains are unduly exposed to toxigenic strains.[26]

[26] Per comments on the draft PEA provided by Ranajit Bandhyopadhyay, IITA.

NO.	DESCRIPTION OF SIGNIFICANT ENVIRONMENTAL ISSUE (AS DETERMINED IN AFLASAFE SCOPING STATEMENT)	DISCUSSION OF ISSUE AND ASSESSMENT OF SIGNIFICANCE
5	Controlled manufacturing processes capable of producing adequate quantities of regionally specific formulations of aflasafe to maintain required application frequency to ensure long-term crop protection.	The long-term efficacy of crop protection through aflatoxin bio-control will depend on the availability of adequate supplies of aflasafe for crop treatment. Although commercial manufacturing in sub-Saharan Africa is currently limited to a single major facility in Nigeria, aflasafe proponents are currently preparing for manufacturing facilities in at least two other countries (Senegal and Kenya). There are a number of factors which may limit aflasafe manufacturing capacity across the region, many of which are beyond the practical control of USAID. The construction and operation of most, if not all, manufacturing facilities will require host-country review and certification/approval by either the cognizant pesticide regulator or an overarching environmental management authority (or both). The requirements for approval may prove a barrier to entry for otherwise qualified manufacturers. Adequate quality assurance and quality control (QA/QC) mechanisms will also need to be instituted as part of the manufacturing process to ensure the availability of aflasafe that is effective and performs to expectations. Finished products must be channeled through reliable and trustworthy input and agro-supply dealer networks and made available to consumers at a competitive price. The *economic sustainability* of aflasafe manufacturing is as important, if not more so, than productive capacity in ensuring adequate supply over the long term. Concerns regarding sustained demand for aflasafe, particularly among smallholder farmers, may be addressed in part through education, awareness building, effective pricing, and, potentially, subsidies or other schemes. From the standpoint of potential adverse environmental effects, neither absolute productive capacity, nor the viability of any underlying economic model by themselves have the potential for negative environmental impacts. While the objective of long-term crop protection drives current production goals, a decline in production and subsequent lapses in application will not lead to an increase in aflatoxin levels beyond those that existed prior to the use of aflasafe; that is to say, aflatoxin levels would not exceed baseline levels if aflasafe use were reduced (or eliminated) as a result of supply constraints. Similar to most agro-inputs, a reduction in aflasafe use will lead to a decrease in the desired effect sought through use of that product; less use of aflasafe means less bio-control of aflatoxin-producing *A. flavus*. While this does not achieve the objective of long-term crop protection, it does not represent an environmental risk beyond that currently facing the stakeholders in affected areas, i.e., aflatoxin levels will not be exacerbated by cessation of aflasafe use once it has begun.
6	The potential for cessation of USAID funding and the potential for toxigenic strains to	Regardless of the funding source, long-term crop protection will depend on a reliable, affordable supply of high-quality aflasafe. The financial model(s) and/or funding streams needed to sustain production can vary and will likely rely relatively less on USAID involvement over time. As such, the potential

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	return with potentially greater toxicity and/or a perception of safe crops that are actually not safe.	cessation of USAID funding does not equate to a lack of aflasafe availability or a fundamental change in its application in the field. More importantly, USAID involvement (or lack thereof) will not lead to the emergence of more toxic strains of *A. flavus* than already exist and that occur naturally. As discussed above, a reduction in aflasafe application means less bio-control of aflatoxin-producing *A. flavus.* So, while USAID funding could impact overall production and availability, any constraints or limitations in aflasafe use will simply lead to less effective aflatoxin control, up to a return to baseline conditions. While re-treatment is needed to maintain the displacement of toxin-producing fungi, the magnitude of application is reduced over time and there is no evidence of toxic strains of *A. flavus* immediately re-establishing themselves in previously treated fields. The perception that crops are safe when they are actually not can stem from a number of circumstances, which might not necessarily be linked to a cessation of USAID funding. Farmer and consumer perceptions of aflasafe-treated crops are problematic, as there is no visible distinction between treated and untreated material. The perception issue persists well beyond USAID control, and will require a coordinated response among aflasafe proponents (see subsequent discussion of marketing and certification efforts). The (mis)perception of unsafe crops as safe <u>may</u> present adverse impacts exceeding those currently faced by affected populations, particularly more vulnerable groups. For example, a family that includes elderly or immunocompromised individuals may decide to purchase and/or cultivate more maize for household consumption based on perceived assurances of aflasafe use generating aflatoxin-free food. This behavior change would stem from general awareness building—and possible demand creation—regarding the presence and impact of aflatoxin, and the benefits of aflasafe use, initiatives that USAID is likely to support as one aspect of APPEAR project implementation. Under this scenario, if aflasafe use is constrained (either through limited production or other factors) to the extent that toxigenic strains of *A. flavus* reemerge on previously treated fields, affected populations that have adapted or grown accustomed to consuming "safe" maize may be at greater risk once the bio-control effect subsides (however, the risk will not be greater than the baseline risk associated with no bio-control efforts). This is particularly true for any groups whose consumption patterns have been significantly shaped by the perceived benefits of aflasafe use; their perception of a "safe" crop underlies individual choices of what to eat, and how much. If food that is thought to be safe is not, and at-risk sub-groups are consuming more of it than they had originally, they are at increased risk of aflatoxin-related illness. This issue warrants long-term environmental mitigation and monitoring over

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		the life of the project and beyond.
7	Availability of robust sampling protocols and analytical methods to test for presence of aflatoxins in treated produce.	This remains one of the most challenging technical aspects of aflasafe manufacture and use. In many regards, it is linked to the perception of crop safety addressed in the previous discussion, particularly the need to establish a sustainable economic model—since any long-term demand for aflasafe will be based on its demonstrable efficacy. However, the availability or lack of availability of effective, accurate protocols and analytical methods does not present the potential for adverse environmental impacts beyond those currently associated with aflatoxin in affected areas. Robust and practical sampling protocols and analytical methods have yet to emerge from the various aflasafe development efforts and stakeholder conversations underway. These include a January 2013 Sampling Protocol Meeting convened in Nairobi (and sponsored by USAID) and ongoing involvement by USDA in an effort to establish a sampling plan that is technically and financially feasible for aflatoxin monitoring in sub-Saharan Africa. Certain aflasafe proponents suggest that the cost of analysis is almost prohibitively expensive and that, considering the product's demonstrated efficacy to date, resources are more wisely spent on aflasafe procurement and promoting widespread use. Existing sampling practices are also especially problematic: by one account taking a single sample (e.g., a single ear of maize, or even selected kernels) and dividing into multiple segments for independent evaluation at different laboratories can result in as many disparate results as segments created. Much of this variability stems from the growth of *A. flavus*, which can cluster in some parts of the sample and be sparse or non-existent in others. Even with the development and/or introduction of a technically sound protocol and corresponding methods, capacity limitations at the local or national levels may hamper effective assessment of aflasafe-treated produce. A dearth of adequately trained personnel or lack of laboratory consumables or facilities could easily impair the efficacy of any produce testing regime. The larger risk associated with the lack of robust sampling protocols and analytical methods is that consumer trust in aflasafe may erode over time. If farmers and grain producers are not able to establish a direct benefit of aflasafe use through accurate aflatoxin monitoring, they will be challenged to realize a premium on their product and recoup investment in aflasafe purchase and application. This undercuts the long-term viability of aflasafe manufacturing, which will require some degree of sustained commercial demand. Individual households using aflasafe and consuming their own aflasafe-treated crops (i.e., smallholder farmers) would likely not be realistic candidates for regular aflatoxin monitoring, even with technology that is

NO.	DESCRIPTION OF SIGNIFICANT ENVIRONMENTAL ISSUE (AS DETERMINED IN AFLASAFE SCOPING STATEMENT)	DISCUSSION OF ISSUE AND ASSESSMENT OF SIGNIFICANCE
		relatively simple and less costly. Jason Sandahl, Senior Program Manager for Food Safety for USDA, indicated that USDA is getting assistance from Andrew Slate, a Research Assistant at North Carolina State University and an expert in agricultural sampling plan modeling.[27] Mr. Slate is in the process of preparing a technical report on sampling protocols in conjunction with the use of aflasafe. The work addresses a key issue associated with sampling and chemical analysis of any sample: the minimization of false positives (rejecting produce when the levels of aflatoxin are not in excess of standards) and false negatives (failing to reject produce when the levels of aflatoxin are in excess of standards). Although false positives and negatives cannot be completely eliminated, the report includes recommended steps that can minimize their probability, including: 1) increasing the size of the sample sent to the laboratory; 2) increasing the number of samples analyzed; 3) increasing the size of the sample analyzed by the laboratory; 4) comminuting (i.e., mechanically reducing particle size) the samples so 80 percent of the sample passes a #20 sieve.[28] In addition, there is currently a sampling and testing protocol (consisting of aflatoxin analysis by rapid quantitative test kits and aflasafe strain identification using microbiological methods) being followed under the AgResults initiative in Nigeria. The chemical testing method will remain in force, but the microbiology testing will cease (since it is expensive and time-consuming) once aflasafe use expands. Further, PACA is creating a testing platform for aflatoxins in five African countries that is expected to provide testing services.[29] While it is encouraging that efforts are in place to establish and implement sampling and analytical procedures that serve to document the efficacy of aflasafe, it is currently unclear how these sampling and analytical procedures might be harmonized with the distribution and use of aflasafe across sub-Saharan Africa.
8	The potential for atoxigenic strains of *A. flavus* in aflasafe to become pathogenic through recombination processes in the environment.	By all accounts, sexual recombination in the environment of the atoxigenic strains of *A. flavus* in aflasafe with existing toxigenic strains is nearly impossible. This effectively precludes the threat that the atoxigenic strains comprising aflasafe may evolve into pathogenic strains once the product is applied and exposed to the spectrum of naturally occurring *A. flavus*. Atoxigenic strains of *A. flavus* have evolved through genetic mutation, mainly deletions in the aflatoxin-producing gene. Most strains are vegetatively incompatible, which minimizes the possibility of recombination. While

27 Personal communication with Jason Sandahl, USDA, 9 June, 2014.

28 E-mail communication with Andrew Slate, 5 September, 2014.

29 Per comments on the draft PEA provided by Ranajit Bandhyopadhyay, IITA.

NO.	DESCRIPTION OF SIGNIFICANT ENVIRONMENTAL ISSUE (AS DETERMINED IN AFLASAFE SCOPING STATEMENT)	DISCUSSION OF ISSUE AND ASSESSMENT OF SIGNIFICANCE
		documented under laboratory conditions, recombination through independent assortment and crossing over is rare in nature, reducing the risk that atoxigenic strains of *A. flavus* in aflasafe may become pathogenic through recombination processes in the environment. Different species and strains of fungi have co-existed for tens of thousands of years; if these types of genetic changes were likely to occur, this phenomenon would be evidenced in the fungi evaluated for aflasafe development. Aflatoxin biosynthesis is also polygenic, meaning it is influenced by interaction of genes from other chromosomes. Therefore recombination and mutation events alone cannot determine toxicity. The aflatoxin-producing gene is highly heritable, and atoxigenic strains reproduce to give rise to the same type. Thus the risk of atoxigenic reverting to toxigenic is rare and can only occur if there is sexual reproduction. Given that *A. flavus* reproduces exclusively by asexual means (consistent with its haploid nature), chances of recombination are rare and the possibility of atoxigenic strains reverting to toxigenic in the environment is remote.
9	The potential for aflasafe application to cause fungal infestation of crops which, while not toxic, may result in crops that are of limited or no nutritional value.	The effective use of aflasafe on aflatoxin-affected crops is predicated on fungal infestation, albeit with strains of *A. flavus* that are not harmful to humans when consumed. The application of aflasafe is intended to displace naturally occurring, toxigenic strains of *A. flavus* and does not lead to an absolute increase in the amount of fungus present on treated crops—the atoxigenic strains will simply prevail (see previous discussion of the "founder effect"). Proponents of aflasafe openly acknowledge that there will "always be fungus on maize."[30] Indeed, this phenomenon underlies the dissemination and efficacy of aflasafe on affected crops. *Aspergillus* in particular is very widely dispersed and can be expected to grow—and does grow—on maize across a range of climatic and geographic zones. Within these areas, it appears that fungal growth is enhanced by crop damage and humid storage conditions. In this vein, aflasafe use should complement ongoing GMPs that minimize physical damage to crops (which could be inflicted by termites; see issue #11) and programs such as AflaSTOP, which is designed to improve storage and drying conditions to minimize fungal growth. While the use of aflasafe may be coupled with other aflatoxin control measures, there is no indication that aflasafe use promotes additional mold on maize relative to maize from untreated fields,[31] regardless of any ramifications on nutritional value. Thus, there is little risk of crop infestation from aflasafe leading to a decline in nutritional value beyond that which may already manifest in affected crops and/or fields. Consequently, aflasafe will not adversely impact the nutritional value of treated crops any more than

[30] Personal communication with Peter Cotty, USDA; 10 July, 2014, via teleconference.

[31] Personal communication with Ranajit Bandyopadhyay, IITA; 10 July, 2014, via teleconference.

NO.	DESCRIPTION OF SIGNIFICANT ENVIRONMENTAL ISSUE (AS DETERMINED IN AFLASAFE SCOPING STATEMENT)	DISCUSSION OF ISSUE AND ASSESSMENT OF SIGNIFICANCE
		untreated crops. However, long-term monitoring of this issue is needed, particularly given the possible role of secondary metabolites, which studies indicate can be produced by some strains of atoxigenic *A. flavus*. An aflatoxin control advocate confirmed that such toxic fungal secondary metabolites (e.g., cyclopiazonic acid [CPA]) can be produced, but also indicated it is possible to test for—and screen out—atoxigenic strains of *A. flavus* that produce these secondary metabolites as part of the strain identification and isolation process that underlies product development.[32] If rigorous screening for secondary metabolites remains integral to the strain identification and isolation process, the risk of such metabolites emerging can be readily mitigated. It should be noted that CPA is not considered to be a potent mycotoxin like the aflatoxins, nor is it considered to be a carcinogen.[33] CPA is currently not regulated on produce and is considered to be toxic in the mg/kg range, in contrast to aflatoxins, which are regulated in the µg/kg range.[34]
10	The scope of introducing aflasafe to the EAC and using the work in the EAC as a model for use of aflasafe across sub-Saharan Africa is such that issues may arise regarding consistency in proper procedural and implementation processes. Thus, a PEA is needed.	Prospective USAID support for aflasafe manufacturing and use across sub-Saharan Africa warrants assessment of potential adverse impacts at a regional level (i.e., per the geographic remit of the USAID Bureau for Africa [USAID/AFR]). This PEA fulfils that mandate, with field work and consultations occurring across four EAC member states: Kenya, Tanzania, Burundi, and Uganda. While necessarily informed by the EAC-centric analysis, the assessment of significant environmental issues in this section of the PEA is applicable in all USAID/AFR countries that may support relevant aflasafe efforts. This assessment and corresponding mitigation and monitoring criteria form the analytical heart of the core PEA. The core PEA is intended for use in East Africa and beyond and should address the potential adverse impacts of aflasafe manufacture and use as they may emerge regardless of country. At the same time, some country-level differences will exist, which may influence the assessment of the significant environmental issues and lead to unique mitigation and monitoring criteria. Concurrent with preparation of the PEA, an East Africa-focused PEA Amendment is being prepared to address issues or considerations that are unique to the four EAC countries in which PEA field work was conducted. Following this model, additional PEA Amendments may be prepared based on the need to evaluate other country-level situations, either at a bilateral or regional scale (e.g., USAID/West Africa, USAID/Southern Africa, USAID/Zambia, etc.).

32 Personal communication with G.J. Benoit Gnonlonfin, Ph.D, Technical Officer, PACA; 11 June, 2014 in Dar es Salaam, Tanzania.

33 Chang, P.K., K.C. Ehrlich and I. Fujii. 2009. Cyclopiazonic Acid Biosynthesis of Aspergillus flavus and Aspergillus oryzae. Toxins, 1, pp. 74-99. Available on the Internet at: http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3202784/

34 Per comments on the draft PEA provided by Ranajit Bandhyopadhyay, IITA.

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		This approach is useful in that each of the four EAC countries visited has its own pest control product or pesticide registration standards and process, which will govern if and how aflasafe is manufactured and used. Assuming aflasafe is deployed, variations in application, sampling protocols, and monitoring may also arise. This type of variability at the country level is most effectively addressed in the form of an Amendment to the core PEA.
11	What effects might use of aflasafe have on termite mounds? Termites and certain fungi have a symbiotic relationship and there is concern that aflasafe may out-compete other species of fungi, such as those involved with termite populations.	Discussion of the potential adverse impacts associated with the possible effect of aflasafe on termite colonies emerged following preparation of the aflasafe Scoping Statement, and was not originally included as a significant environmental issue requiring evaluation at the PEA level. This issue arose within USAID following circulation of the Scoping Statement and was subsequently included for more complete assessment. The underlying concern is that the introduction of aflasafe may alter the symbiotic relationship that termites share with other fungi, most notably *Termitomyces*. The alteration of this relationship could impair ecosystem services that termites provide to farmers in arid and semi-arid environments, such as the management of soil fertility and rehabilitation of degraded soils.[35] The potential for adverse impacts of aflasafe use on other, termite-friendly fungi is likely predicated on there being either an increase in overall *A. flavus* levels owing to the application of aflasafe, or the potential for the product's constituent atoxigenic strains to dominate *Termitomyces* and related genera. Taking into account the competitive displacement by which aflasafe operates, effective use of the product should not lead to an absolute increase in *A. flavus* levels in the surrounding environment—the atoxigenic strains simply dominate the ambient toxigenic strains. In this regard there appears to be little risk of aflasafe application altering the level *A. flavus* already present in termite gardens. While overall *A. flavus* levels may not increase due to aflasafe use, *Aspergillus* generally pose a threat to termite mound ecosystems, with Shaw (1992) indicating that the comb formed by *Termitomyces* is not a good competitor and can be rapidly dominated by *Aspergillus*.[36] At the same time, aflasafe proponents observe that fungi such as *Termitomyces* have co-existed with *Aspergillus* for thousands of years and the use of aflasafe does not change the ecosystem with regard to fungal competitiveness. In other words, if *Termitomyces* could exist with toxigenic strains of *A. flavus* nearby, it can exist with atoxigenic strains of *A. flavus* nearby.

[35] Influence of termites on ecosystem functioning. Ecosystem services provided by termites. European Journal of Soil Biology. Jouquet, et al. Volume 47, Issue 4, July–August 2011, Pages 215–222

[36] Shaw, P.J.A. 1992. Fungi, Fungivores, and Fungal Food Webs. In <u>The Fungal Community: Its Organization and Role in the Ecosystem</u>, Second Edition, G.C. Carroll and D.T. Wicklow (Eds.). Marcel Dekker, Inc., New York.

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		According to *Biology of Termites* (Krishna and Weesner, eds.), the direct effects of *A. flavus* on termites will depend on the type of termites and the strains.[37] Some strains can act as termite pathogens while others can be non-toxic or even provide nutritional benefits. *A. flavus* has been demonstrated as pathogenic to termites in the United States, where its use as a termiticide to prevent damage to structures and building sites was patented in the 1960s.[38] Recent research, however, asserts that such termite bio-control has generally been ineffective, with Chouvenc et al. stating in 2011 that "conclusions frequently expressed have been misleading to some extent, or at least overly optimistic, about the potential for application of biological control to termites."[39] A practical consideration also exists—the extent to which termite mounds persist on cultivated fields; many farmers are likely to remove and contain mounds as part of the normal field preparation and cultivation cycles, particularly in more arid climates. In these circumstances, termite mounds would rarely receive direct treatment with aflasafe. Mounds in the vicinity of aflasafe-treated fields are likely to receive some amount of atoxigenic *A. flavus* through the dispersal of spores once aflasafe is applied and begins to disseminate in the local environment. For farmers who choose to maintain termite mounds in cultivated areas, and who may apply aflasafe for aflatoxin control, the potential impact of aflasafe application on termite mounds remains uncertain. A further link between termites and aflatoxin exists since termites (among other insects) can cause damage to crops, which in turn encourages fungal growth, including that of *A. flavus.* The issue of whether aflasafe competes with other fungi or just other strains of *A. flavus*, as well as the potential impact on termite mounds warrants long-term monitoring. Additionally, a possible association exists between aflasafe treatment and an increase in termite prevalence versus a no-treatment, no-aflatoxin baseline.[40] This, too, warrants further investigation and resolution.
12	What are the processes in place regarding marketing, certification, and/or distribution of	This issue also emerged following preparation of the aflasafe Scoping Statement. However, this question was raised by the PEA team as it sought to understand the interrelationship between the marketability and commercial success of aflasafe, and longer-term production of an aflatoxin-free food

[37] Krishna and Weesner. 1969-1970. Biology of Termites, Vol. 1 and 2, Academic Press, New York. Kumar Krishna and Frances M. Weesner, eds.

[38] United States Patent 3,249,494 COMBATING TERMITES WITH ASPERGILLUS FLAVUS. Accessed online 22 July, 2014 at: http://www.google.com/patents/US3249494

[39] Chouvenc, T., Su, N. and Grace, J. Fifty years of attempted biological control of termites – Analysis of a failure. Biological Control 59 (2011) 69–82.

[40] Personal communication with G.J. Benoit Gnonlonfin, Ph.D, Technical Officer, PACA; 11 June, 2014 in Dar es Salaam, Tanzania.

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	products coming from aflasafe-treated fields?	supply. It reflects concerns over assurances of the efficacy of aflasafe on treated crops and the integrity of those products as they proceed through the value chain. It also underscores farmers' needs to recoup investment in aflasafe purchase and application and the mechanisms by which aflasafe-treated crops can command a premium at various stages following harvest; this will be integral to the economic viability of aflasafe manufacture and use.[41] The product's economic viability will have direct bearing on several scenarios related to the reduced availability of aflasafe and corresponding decline in rates of application. The most germane of these are discussed above, including the possible (mis)perception of unsafe food as safe. Inadequacies in the marketing, certification and/or distribution of aflasafe-treated products do present the potential for adverse impacts on human health. Potential adverse impacts may result when: 1. Products are marketed, certified or distributed with an aflasafe qualification, but have actually *not* been treated with aflasafe, or have received inferior treatment (e.g., through use of a counterfeit product,[42] or as a result of poor or incorrect application of the bona fide product). The marketed product might contain little or no aflatoxin but might not provide the full value of aflasafe use. It is possible such misrepresentation could result from accident or oversight. Or this might occur as a result of inadequate farmer training, the use of poorly conceived or executed sampling protocols or analytical methods (see above), or fraud. 2. If aflasafe use and aflasafe-treated crops fail to command a premium in national, and potentially international markets, there will be little incentive for sustained large-scale use of the product. Effective marketing, certification, and distribution strategies and practices will be central to creating and maintaining demand for aflasafe-treated crops. Without such demand, the ability of aflasafe manufacturers to continue to invest in aflasafe production and distribution will decrease. As discussed above, constraints in aflasafe supply may lead to a decrease in aflasafe application and re-emergence of the toxigenic strains of *A. flavus*. Although the total amount of toxigenic *A. flavus* would not exceed that seen prior to the use of aflasafe (i.e., it would not exceed baseline levels), the misperception that a product had been properly treated with aflasafe could pose a threat to certain vulnerable populations who have changed consumption patterns based on the product's perceived efficacy.

[41] Conversely, Kola Masha, Managing Directing of Doreo Partners in Nigeria, suggests targeting individuals who *have already lost money* due to contaminated produce, rather than those who may seek a premium upon harvest.

[42] The issue of counterfeit pesticides is an area of increasing concern for USAID. A recent "Research Readout" entitled *Counterfeiting in African Agriculture Inputs – Challenges & Solutions*, prepared by the Bill and Melinda Gates Foundation in collaboration with Monitor Deloitte, provides an excellent summary of the nature of the problem and potential solutions. This document is available for forwarding upon request.

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		In either case, effective marketing, certification and distribution efforts will be needed to promote long-term availability and production of food that is safe from aflatoxin. The role of state regulation must also be factored into this discussion, though the variables associated with the potential involvement of national or local agriculture or food safety authorities across sub-Saharan Africa are too complex to address in the context of this PEA. Rather, these types of issues will need to be addressed at the country level in the course of developing the regional and or/country-specific PEA Amendments. At a minimum, countries could reasonably seek to impose restrictions on contaminated produce or confer certification status on produce that is free from aflatoxins, thereby increasing the value of aflasafe-treated crops. Certification and marketing efforts for aflatoxin-free products are in their infancy. Regional efforts at a common aflatoxin labeling convention or standard (e.g., at the EAC, COMESA, or ECOWAS level) may help drive aflasafe use and production of an aflatoxin-free food supply. However, even aflasafe proponents admit that regional initiatives for aflasafe-related labeling present a profound challenge, with the integration of smallholder farmers presenting a particular obstacle.[43] At least initially, subsidies—coupled with significant investment in awareness building—will be needed to propel commercialization of aflasafe. Support and advocacy among agricultural extension agents and the donor community will be necessary. Some form of effective product differentiation will be necessary to ensure the sustained manufacture and use of aflasafe, and specialized marketing, certification and/or distribution processes can be expected to play a significant role in establishing that distinction. USAID will need to actively participate in efforts to create a favorable market environment for the widespread adoption of aflasafe, strengthening uptake and production of an aflatoxin-safe food supply.

[43] Personal communication with Francesca Nelson, Senior Food Security & Nutrition Advisor, IITA; 5 June, 2014 in Dar es Salaam, Tanzania.

SECTION 6: ANALYSIS OF ALTERNATIVES TO USAID SUPPORT FOR THE MANUFACTURE AND USE OF AFLASAFE, AN AFLATOXIN BIO-CONTROL PRODUCT.

Based on the findings and recommendations of this assessment, and consistent with Agency environmental procedures, USAID may consider alternative approaches to combating aflatoxin in sub-Saharan Africa. The analysis of alternatives presents several scenarios in which USAID may support aflatoxin-related programming that does *not* entail the manufacture, field testing, and use of a bio-control product (i.e., aflasafe). These alternatives align broadly with the development objectives reflected in the APPEAR SOW, retaining focus on aflatoxin control and increased farm incomes and food security in the region.

The product aflasafe represents the only aflatoxin bio-control technology currently suitable for use in Africa. As such, any sustained USAID support for aflatoxin bio-control efforts will necessarily involve aflasafe, at least for the foreseeable future. Alternatives to aflasafe use therefore move the focus away from bio-control efforts in general; alternatives to aflasafe equate to alternatives to bio-control.

Aflatoxin control can take numerous forms, most notably, enhanced post-harvest storage and handling practices (drying practices, in particular), such as those implemented through the AflaSTOP project. USAID support for these and related activities is documented throughout this assessment. At a minimum, bio-control achieved through aflasafe use is one element of a broader aflatoxin reduction (or elimination) strategy.

PROPOSED ACTION:

Through the APPEAR project, and potentially similar mechanisms, USAID will fund the manufacture, distribution, and use of aflasafe, an aflatoxin bio-control product for which registration and commercialization is sought in various countries across sub-Saharan Africa. An analysis of the potential impacts of aflasafe manufacturing, distribution, and use on the environment is presented in the preceding section of this PEA. The proposed action is consistent with the APPEAR SOW and reflects current USAID programming to support aflatoxin control in the region.

ALTERNATIVE #1:

Development and promotion of new non-bio-control aflatoxin reduction technologies. While low-cost post-harvest storages technologies (e.g., solar driers, storage bags) are recognized as an effective means of controlling the proliferation of *A. flavus*, USAID may opt to seek the next generation of such products and technologies in lieu of bio-control efforts. This type of investment could be implemented via an "aflatoxin innovation laboratory," or similar effort; an approach taken by the USAID Bureau for Food Security to promote crop-specific (or in this case, pest-specific) solutions to increased agricultural productivity. The innovation laboratories typically support small-scale and entrepreneurial approaches to a specific food security challenge. In this context, USAID could offer a test-bed for the development and validation of new aflatoxin control techniques, some of which may offer benefits on par with or beyond those associated with the use of aflasafe. These may or may not focus on post-harvest interventions; the objective would be to look beyond the current set of offerings and identify and invest in the most promising innovations.

RELATIVE ADVANTAGES OF THIS ALTERNATIVE:

- Fosters new technologies for aflatoxin control;
- Broadens focus beyond bio-pesticide production and use;
- Small-scale technologies emerging from innovation labs are often intended to be low-cost and designed for accessibility and ease of use;
- Addresses aflatoxin control in Africa by engaging new stakeholders.

RELATIVE DISADVANTAGES OF THIS ALTERNATIVE:

- Uncertainty regarding the viability and/or cost-effectiveness of emerging approaches to aflatoxin control;
- Opportunity cost of eschewing proven bio-control measures achieved through aflasafe use.

ALTERNATIVE #2:

Development and promotion of aflatoxin-resistant varieties of maize and other target crops. This alternative emphasizes the introduction of new crop varieties that resist *A. flavus* contamination and/or aflatoxin production, either through cross breeding, or recombinant DNA methods (i.e., developing a genetically modified organism [GMO]). The availability of such varieties may obviate the need for bio-control or other aflatoxin control measures. USAID regularly supports the development of transgenic or GMO technologies as one means of improving food security and increasing the value of agricultural production. Existing efforts in this area could be extended to the introduction of an aflatoxin-resistant variety of maize that would not require application of a bio-control product or the use of post-harvest and storage GMPs. Although USAID is at present funding aflatoxin-resistance breeding efforts, the progress of these activities is such that they currently do not represent a viable alternative to the demonstrated success of aflasafe.

RELATIVE ADVANTAGES OF THIS ALTERNATIVE:

- May significantly reduce or eliminate need for bio-control measures (and specialized post-harvest and/or storage techniques);
- May simplify aflatoxin control measures for target farmers in affected regions;
- Could ultimately prove more effective in combating aflatoxin.

RELATIVE DISADVANTAGES OF THIS ALTERNATIVE:

- The expense and time (likely years) required to mount this type of plant science initiative may leave immediate aflatoxin concerns unaddressed;
- Development of resistant varieties may not prove an effective means of aflatoxin control in Africa;
- Appropriate use of any resistant varieties may prove too costly or complex for widespread adoption;
- The potential adverse impacts of a widespread mistrust of GMOs and the potential for poor maize quality, as suggested by attempts to increase maize output for ethanol production through genetically modified maize.[44]

ALTERNATIVE #3—THE "NO ACTION" ALTERNATIVE:

Despite the availability of alternate approaches to aflatoxin control, USAID may opt to simply not support the commercialization of a bio-control product, at the same time forgoing additional investment in related programming (such as those described in Alternatives #1 and #2). This is the "no action" alternative, and is intended to assess the potential impact of USAID deciding to not fund broader aflasafe activities, with all other factors held constant. In the no action scenario, USAID would continue to support the existing range of aflatoxin control efforts, with the exception of aflasafe-related initiatives. At the same time, elimination of aflasafe funding would not be offset by spending in other areas of aflatoxin control.

It is worth noting that support for aflasafe development and use in sub-Saharan Africa will likely continue regardless of USAID involvement. While current USAID support is vital to the isolation of atoxigenic strains and other laboratory-based efforts needed for product development, particularly in East Africa, the long-term commercial potential of this technology is likely to continue to attract a variety of interests, both private and public. One potential impact of USAID opting against longer-term support for aflasafe is increased reliance on corporate or other for-profit entities for the financial backing needed to commercialize the product. Based

[44] The New York Times. 2011. U.S. Approves Corn Modified for Ethanol. Available on the Internet at: http://www.nytimes.com/2011/02/12/business/12corn.html?_r=0

on the need to recoup investment, this type of funding could limit the availability of aflasafe among the poorest farms/households.

The involvement of USAID—and other donors and development agencies—compels equitable access to this and similar technologies, consistent with the goals of improving human health and accelerating economic growth. This development mandate, however, does not preclude the need for aflasafe to also attain economic viability in multiple markets. It is at minimum a balance, one that even the most ardent proponents of aflasafe are still working to understand. The trade-off between public good and sustainability (economic or otherwise) is manifest in most development programming, and aflasafe is no exception.

The most immediate impact of USAID opting against support for the manufacture, field testing, and use of aflasafe—where this capacity exists—is the likely delay in commercial availability of the product to farmers and households at risk of continued aflatoxin poisoning. As noted, aflasafe will likely count a range of supporters in its development and use over the long term. In the short term, though, a lack of USAID funding could slow the process by which aflasafe is registered for use in the partner country and made available at competitive prices within a reliable agricultural input supply chain. This will prolong response to what many view as a public health priority. The presence of aflatoxin "hotspots" in several countries underscores the urgency of rolling out effective bio-control measures.

The potential benefits of the no action alternative include cost savings to USAID, including costs related directly to the manufacture, field testing, and use of aflasafe, as well as the cost of environmental mitigation and monitoring consistent with the recommendations of this assessment. USAID may also benefit from reduced liability for potential risks to human health and the environment. By limiting aflatoxin-related programming to existing non-bio-control interventions (e.g., post-harvest techniques, such as those promoted through the AflaSTOP project), USAID may ultimately support the most cost-effective and sustainable methods of aflatoxin control in sub-Saharan Africa.

RELATIVE ADVANTAGES OF THE 'NO ACTION ALTERNATIVE':

- Reduces costs and perceived risks associated with aflasafe programming;
- Enables USAID to focus on interventions that may prove more cost-effective and sustainable for controlling aflatoxin.

RELATIVE DISADVANTAGES OF THE 'NO ACTION ALTERNATIVE':

- Investment in promising aflatoxin bio-control technology is missed;
- Crop handling and post-harvest techniques to limit crop damage and prevent or control aflatoxin may be difficult to successfully implement over the long run and across varying climatic zones;
- Commercial availability of aflasafe may be delayed at the expense of public health and food security development objectives;
- Commercial interests may take the lead in continued development and promotion of aflasafe.

CONCLUSION

It is the opinion of this assessment team that the manufacture, distribution, and use of aflasafe presents a unique and compelling opportunity for the control of aflatoxins in sub-Saharan Africa. The benefits to public health and food security likely to be achieved through the use of this bio-control technology are substantial. At the same time, assessment of the potential adverse impacts of aflasafe use indicates that a prudent approach to mitigation and monitoring can limit to an acceptable level any potentially harmful effects of aflasafe on human health and the environment.

If USAID decides to implement the proposed action, its support for aflasafe manufacture, distribution and use will ideally remain linked to other aflatoxin control programs and strategies. Emerging technologies, such as those suggested by the presentation of alternatives above, should be viewed as possible and promising complements to aflasafe use. As awareness of aflatoxins increases in sub-Saharan Africa and USAID seeks to improve agricultural systems and public health in specific countries, the use of aflasafe should be viewed as a viable means of helping to meet these development objectives.

SECTION 7: ENVIRONMENTAL MITIGATION AND MONITORING FRAMEWORK

Section 7.1 introduces the environmental mitigation and monitoring framework (EMMF) that will govern environmentally sound design and management of the proposed bio-control activities. This will include overview of the EMMF approach, and explanation of how this approach maps to the issues of concern identified in the Scoping Statement.

Section 7.2 further develops the environmental mitigation roles and responsibilities of USAID and its implementing partners (IPs) throughout implementation.

Section 7.3 defines the monitoring requirements.

1. OVERVIEW OF THE EMMF

Environmental management of the manufacture and use of aflasafe will be governed by the EMMF established in this section. The manufacture and use of aflasafe can be translated into a series of lifecycle phases. These phases, in turn, serve as the logical benchmarks against which the EMMF will operate. Specifically, the EMMF for manufacture and use of aflasafe aligns the environmental impacts and accordant mitigation and monitoring conditions with these lifecycle phases. Attachment D to this PEA provides a suite of template Environmental Mitigation and Monitoring Plans (EMMPs), which are phase-specific and meant to be tailored to the country-specific implementation conditions in each country seeking to introduce aflasafe manufacture and use. The EMMF implementation process, including the general EMMF implementation requirements, is further defined in section 7.2.

The specific lifecycle phases are identified and defined below:

1. **<u>Bio-control Research</u>** - This entails identifying country- and region-specific strains of atoxigenic *A. flavus* for use in country- and region-specific aflasafe products. As discussed in the APPEAR SOW, "Biocontrol, Year 1, the identification of strains is part of the Categorical Exclusion." Thus, while this is an essential lifecycle phase of aflasafe manufacture and use, it is not governed by this PEA.

2. **<u>Awareness Raising and Demand Creation</u>** – This phase encompasses outreach and capacity building efforts at both the policy and smallholder farmer levels, as well as engagement with additional stakeholders along the agricultural value chain.

   Awareness campaigns will emphasize the health impacts of aflatoxins, introduce strategies and GMPs beyond bio-control to help reduce aflatoxins, and familiarize potential consumers and policymakers with the benefits aflasafe can have in reducing the risks from aflatoxins and supporting the production of safe food. These campaigns will deliver accurate and balanced information, ensuring that aflasafe is understood as a tool but not a panacea for management of aflatoxins.

3. **<u>Registration of aflasafe</u>** – Registration of aflasafe entails preparation of a complete dossier for registration of the bio-pesticide in a manner both consistent with any regional guidance for bio-pesticide registration and all host-country policies governing the registration and use of bio-pesticides. Common elements of the registration process include the provision of rigorous scientific support for the efficacy of the proposed bio-pesticide, field testing and evaluation of the product in the host country, and approval by a host country's pesticide registration board. Specific requirements will vary by country. To the extent host-country policies are developed and accessible, these are provided in Amendments to this PEA. The registration process typically involves registration of not only the bio-pesticide active ingredient, but also a manufacturing process and a manufacturing facility, as discussed in the following phase.

4. **Establishment of Manufacturing** – The establishment of manufacturing facilities for the production of aflasafe is a multi-step process. Candidate sites must be selected and screened to ensure their long-term suitability for the intended purpose. Where host-country permits are required, the permitting process must strictly comply with country-specific requirements. Upon receipt of appropriate permitting, construction or installation of the facility can proceed.

5. **Manufacturing Processes and Production of aflasafe** – Manufacturing processes for aflasafe include the heating of the medium (currently sorghum seed) for sterilization, followed by a coating process that includes the atoxigenic strains of *A. flavus*; quality testing, and packaging of the finished product. The leading process in use at time of the preparation of this PEA entails suspending the atoxigenic strains of *A. flavus* in a polymeric adherent/dye mixture that is applied to the sorghum in a commercial seed coater.

6. **Post-Production Storage and Distribution** – Following production, on-site storage of manufactured aflasafe requires sufficient space to accommodate stock, and sufficient capacity to safely manage inventory. As aflasafe use increases, transport and distribution of aflasafe necessitates access to reliable vehicles and access to areas with demand. It also requires reliable distributors or vendors that can safely and effectively manage the product and supply it to end users. Safe and effective management may include training on proper application techniques, household storage, and disposal. Additionally, considerations such as certification, labeling, and branding may increase efficacy of post-production distribution and retail.

7. **Use of aflasafe** – Use of aflasafe involves consumer purchase, handling, and application on fields. In turn, it includes all household storage and management of the product.

8. **Food Safety Surveillance** – Food safety surveillance comprises short- and long-term monitoring and evaluation of the efficacy of aflasafe manufacture and use. The specific monitoring criteria for aflasafe manufacture and use will be established in Section 7.3.

Table 5 maps the twelve issues of concern assessed in Section 5 against the eight lifecycle phases defined above. The cells demarcated with an "X" represent those phases for which environmental impacts, and associated environmental management steps related to the twelve issues of concern, are expected to manifest.

The mapping in Table 5 translates the potential environmental impacts associated with each of the issues of concern to issues that must be considered at specific phases of implementation. In defining the timing and application of environmental safeguards, this approach is meant to align with the natural progression of activities associated with aflasafe manufacture and use. In effect, this shows which phase-specific EMMP(s) will provide environmental management guidance for the assessed issues of concern.

Table 5: Potential Occurrence of Significant Environmental Issues by aflasafe Lifecycle Phase

	BIO-CONTROL RESEARCH	AWARENESS RAISING AND DEMAND CREATION	REGISTRATION OF AFLASAFE	ESTABLISHMENT OF MANUFACTURING	MANUFACTURING PROCESSES AND PRODUCTION OF AFLASAFE	POST-PRODUCTION STORAGE AND DISTRIBUTION	USE OF AFLASAFE	FOOD SAFETY SURVEILLANCE
1. Toxigenic strains of *A. flavus* may contaminate aflasafe and compete for growth during formulation manufacture or use.					X		X	
2. What effect might localized modular manufacturing locations have on sensitive subpopulations, such as those with compromised immune systems (either as workers involved in the manufacturing process or as nearby residents)?				X	X			
3. The ability of aflasafe to effectively outcompete growth of other *Aspergillus* strains that may produce aflatoxins, such as *A. parasiticus* and *A. tamarii*.							X	
4. Adherence by farmers and grain storage warehouse managers to all relevant GMPs to reduce risk of growth of the toxigenic strains of *A. flavus* during aflasafe storage and use in the field.						X	X	
5. Controlled manufacturing processes capable of producing adequate quantities of regionally specific formulations of aflasafe to maintain required application frequency to ensure long-term crop protection.		X		X	X			

	BIO-CONTROL RESEARCH	AWARENESS RAISING AND DEMAND CREATION	REGISTRATION OF AFLASAFE	ESTABLISHMENT OF MANUFACTURING	MANUFACTURING PROCESSES AND PRODUCTION OF AFLASAFE	POST-PRODUCTION STORAGE AND DISTRIBUTION	USE OF AFLASAFE	FOOD SAFETY SURVEILLANCE
6. The potential for cessation of USAID funding and the potential for toxigenic strains to return with potentially greater toxicity and/or a perception of safe crops that are actually not safe.		X						X
7. Availability of robust sampling protocols for analytical methods to test for presence of aflatoxins in treated produce.								X
8. The potential for atoxigenic strains of *A. flavus* in aflasafe to become pathogenic through recombination processes in the environment.							X	X
9. The potential for aflasafe application to cause fungal infestation of crops which, while not toxic, may result in crops that are of limited or no nutritional value.							X	X
10. The scope of introducing aflasafe to the EAC and using the work in the EAC as a model for use of aflasafe across sub-Saharan Africa is such that issues may arise regarding consistency in proper procedural and implementation processes. Thus, a PEA is needed.	X	X	X	X	X	X	X	X
11. What effects might use of aflasafe have on termite mounds? Termites and certain fungi have a							X	

	BIO-CONTROL RESEARCH	AWARENESS RAISING AND DEMAND CREATION	REGISTRATION OF AFLASAFE	ESTABLISHMENT OF MANUFACTURING	MANUFACTURING PROCESSES AND PRODUCTION OF AFLASAFE	POST-PRODUCTION STORAGE AND DISTRIBUTION	USE OF AFLASAFE	FOOD SAFETY SURVEILLANCE
symbiotic relationship and there is concern that aflasafe may out-compete other species of fungi, such as those involved with termite populations.								
12. What are the processes in place regarding marketing, certification, and/or distribution of products coming from aflasafe-treated fields?		X			X	X	X	X

2. IMPLEMENTATION OF ENVIRONMENTAL MITIGATION

As introduced in Section 7.1, the EMMF will be logically benchmarked against the lifecycle phases of aflasafe manufacture and use. The establishment of these phases allows for phase-specific EMMPs to be developed and to align with general program implementation.

This section defines the process and criteria for effective implementation of the EMMF. On the whole, for EMMF implementation to be effective, the key actors involved need clear understanding of the following:

1) the steps incumbent to environmental management;
2) the implications (i.e., required outcomes) of each step;
3) the timing of each step;
4) the frequency with which each step must be applied; and
5) the parties responsible for ensuring the steps are performed.

The general EMMF implementation requirements are outlined below. Compliance with the PEA mandates adherence to these conditions:

1. ***The Implementing Partner (IP) is responsible for:***
    a. **The development of all country-specific, phase-specific EMMPs**, which must be prepared to address the environmental issues established in Tables 6 and 7 below in accordance with the environmental mitigation strategy presented in those same tables.
    b. **The development of EMMPs for aspects of implementation beyond aflasafe manufacture and use that have the potential to cause adverse impact without adequate environmental mitigation**. For example, where agricultural GMPs are recommended, the IP will need to develop EMMPs that enumerate the specific GMPs for the country in question, given the environmental conditions in-country.
    c. **Adherence to the conditions established in this PEA, as well as those established in the country- and phase-specific EMMPs.** In cases where the IP uses subcontractors or sub-grantees to perform designated tasks covered by this PEA, the IP will be responsible for ensuring the sub-contractor or grantee has sufficient capacity to perform all required environmental management, and that the sub-contractor or grantee in fact fulfills all such requirements.
    d. **Assessing the need for capacity building and training** pertaining to aflasafe manufacture and use. Section 8 of this PEA provides recommended guidance for development and implementation of a training and capacity building program related to aflasafe manufacture and use. The IP will likewise be responsible for preparation of country-specific training and capacity building curricula.
    e. **Provision of briefings on EMMF implementation** to the USAID Agreement Officer's Representative or Contracting Officer's Representative (AOR/COR), Regional Environmental Officer or Regional Environmental Advisor (REO/A), and (where applicable) Mission Environmental Officer (MEO). The briefings should detail both successes and challenges faced in implementing the EMMF, suggested adjustments or modifications to the EMMF implementation process, and overall status of environmental management. Any formal modifications to the EMMF implementation process require REO/A and BEO approval.

2. ***USAID REO/As and MEOs:***
    a. **Approval of all EMMPs developed by the IPs.** Specifically, in all cases, REO/A approval will be required. In implementation countries with USAID missions, MEO approval will also be required.

b. **Approval of all training and capacity building curricula developed.** Specifically, in all cases, REA/OREO/A approval will be required. In implementation countries with USAID missions, MEO approval will also be required.
c. **At minimum, semi-annual site visits to areas of project implementation**, including, but not limited to, training and capacity building activities (e.g., demonstration plots) and manufacturing and agro-retail facilities. These responsibilities can be divided up among REO/As, MEOs, and other local USAID environmental officers to improve effectiveness. Findings from these visits should be synthesized and included in annual environmental reporting.
d. **Approval of all standard operating procedures (SOPs) for manufacturing facilities to ensure adherence to occupational safety and health standards as well as to reduce risk of environmental impact as discussed in Table 6.**

3. **The USAID AOR/CORs will be responsible for:**
   a. Ensuring IP compliance with this PEA as well as the conditions enumerated in the country- and phase-specific EMMPs.
   b. Ensuring that the IP complies with all applicable host-country and regional laws and regulations and coordinates with all appropriate host-country and regional institutions.
   c. At minimum, semi-annual site visits to areas of project implementation, including but not limited to training and capacity building activities (e.g., demonstration plots) and manufacturing and agro-retail facilities. Findings from these visits should be synthesized and included in annual environmental reporting.
   d. Reporting any instances of non-compliance by the IP to the MEO and REO/A.

To provide a contextual framework for the application of the general EMMF implementation requirements, Table 6 summarizes the primary environmental and social impacts of concern identified by this PEA for each lifecycle phase, as well as a specific mitigation strategy for effectively managing each of these potential impacts.

Table 6: Primary Environmental and Social Impacts of Concern

LIFECYCLE PHASE	ENVIRONMENTAL/SOCIAL IMPACTS AT PHASE	ENVIRONMENTAL MITIGATION STRATEGY
1. Bio-control Research	Bio-control research (i.e., strain identification and isolation) is not covered by this PEA.	Bio-control research (i.e., strain identification and isolation) is not covered by this PEA.
2. Awareness Raising and Demand Creation	Unrealistic expectations about aflasafe leading to unsafe consumption or dissatisfied users of the product	Awareness raising must underscore that aflasafe is not a quick-fix solution; instead, aflasafe should be promoted as one tool within a set of control resources for aflatoxins. Realistic expectations must be established about the efficacy of aflasafe and the parameters for use in order to maximize beneficial results (e.g., while aflasafe is likely to reduce aflatoxin-levels during first harvest relative to the baseline, aflasafe does not necessarily make food safe immediately and application may be required over multiple planting seasons).

LIFECYCLE PHASE	ENVIRONMENTAL/SOCIAL IMPACTS AT PHASE	ENVIRONMENTAL MITIGATION STRATEGY
	Insufficient awareness or demand leading to lack of market differentiation for treated and/or safer products, undermining trust among consumers in aflasafe as a viable bio-control approach.	As the product popularizes, certification/labelling/branding requirements will be needed to legitimize the use of the product via market differentiation and, eventually, establish a product premium.
3. Registration of aflasafe	No potentially significant adverse environmental or social impacts pertaining to the manufacture or use of aflasafe are anticipated at this lifecycle phase.	Adherence to the host-country's (and any regional) bio-pesticide registration processes will be needed to ensure registration of a safe product in a manner that has little to no adverse environmental impact.
4. Establishment of Manufacturing	Improper site selection or insufficient controls at the facility leading to airborne fungal exposure by local immunocompromised populations.	Manufacturing facilities must comply with basic worker safety and environmental controls, including air handling equipment, and wastewater and solid waste management. These requirements must be met during pre-construction planning. Certain manufacturing processes can also be implemented to minimize airborne fungal exposure in the manufacturing facilities and within the environment in the area surrounding the manufacturing facilities. For example, IITA has revised its aflasafe manufacturing process to limit the dispersal of spores: after the sorghum is roasted for sterilization, the sorghum is treated with a suspension of atoxigenic *A. flavus*, polymeric adherent and dye in a commercial seed coater. In this way, the spores are contained within the adherent/dye suspension which minimizes dispersal of the spores.
	Poor siting or construction practices lead to undue environmental impacts (e.g., siltation of area water bodies, soil erosion or degradation).	The construction of manufacturing facilities must comply with all applicable host-country review and certification/approval requirements.
	Poor site selection can make post-production distribution to target beneficiaries onerous, inefficient, or otherwise challenged.	Site selection requirements for manufacturing facilities will need to account for target beneficiaries (i.e., smallholder farmers in areas with highest recorded levels of aflatoxins, and drivers of demand such as poultry farmers or others with vested economic interests in the gains realized from aflasafe manufacture and use).
5. Manufacturing Processes and aflasafe Production	Production of low-quality product through improper adherence to manufacturing processes, limiting effectiveness upon application.	Adequate QA/QC mechanisms will need to be instituted as part of the manufacturing process to ensure the availability of aflasafe that is effective and performs to expectations. To ensure this, each aflasafe manufacturing facility must prepare, maintain, and regularly update a SOPs

LIFECYCLE PHASE	ENVIRONMENTAL/SOCIAL IMPACTS AT PHASE	ENVIRONMENTAL MITIGATION STRATEGY
		document that addresses all operational aspects of the facility, including, but not limited to, maintenance and security procedures and scheduling, and all technical procedural steps to be taken during the production of aflasafe. Each batch of aflasafe should maintain tracking systems for raw materials used (including source, cost, and Lot no's, where applicable), process steps implemented, and production volumes. Additionally, the manufacturing facility should have an on-site laboratory or an effective system to evaluate the quality of the aflasafe upon production, prior to packaging and distribution.
	Improper packaging increasing risk of product contamination.	Basic, low-cost facility and process controls in place to contain aflasafe and its active ingredients, preventing dispersal to or contamination of the local environment. System to prevent potential adverse impacts on nearby sensitive or immunocompromised populations.
6. Post-Production Storage and Distribution	Unreliable agro-suppliers could contaminate the product or distribute artificial or fraudulent proxies.	Protocol to channel finished product through reliable and trustworthy input and agro-supply dealer networks and made available to consumers at a competitive price.
	Disaggregated value chains, or weakened infrastructure, could lead to inefficient or ineffective distribution channels.	Existing distribution channels, such as Ministry of Agriculture Extension Services or other agricultural support mechanisms, should be leveraged where possible to reduce costs and potential inefficiencies in distribution.
7. Use of aflasafe	Improper application technique could reduce, or eliminate, efficacy of aflasafe (e.g., applying the product too late).	Training/demonstrations required on proper application, handling, storage, and disposal of aflasafe incorporated into aflasafe manufacture and use activities. Ensure ministry of agriculture extension services, or like agricultural support mechanisms are beneficiaries of awareness-raising and capacity building efforts on aflatoxins and aflasafe. Utilize a "training the trainers" program to empower downstream training on proper use of aflasafe.
	Improper storage could expose the product to contamination or early expiration.	Training/demonstrations required on proper application, handling, storage, and dispose of aflasafe for aflasafe manufacture and use activities. Inventory management systems in place to help identify storage issues and track potential expiration of stored products. As products near expiration, if they are unlikely to be used at current location, re-distribution should be explored.

LIFECYCLE PHASE	ENVIRONMENTAL/SOCIAL IMPACTS AT PHASE	ENVIRONMENTAL MITIGATION STRATEGY
8. Food Safety Surveillance	The misperception of unsafe crops as safe may present adverse impacts that would not otherwise be faced by impacted populations, particularly more vulnerable groups.	Because aflasafe has been shown to have an "area effect"[45] (meaning that it reduces levels of aflatoxins in the fields applied as well as adjacent and area fields), establish life-of-project monitoring that focuses on comparisons of the levels of aflatoxins in treated areas versus those in untreated areas. The monitoring parameters are further developed in Section 7.3 of this PEA.
	While unlikely, aflasafe could produce harmful secondary metabolites if there were a failure in strain identification and/or isolation.	Conduct epidemiological surveys to track prevalence of diseases linked to acute and chronic exposure to aflatoxins throughout life-of-project.

Table 7 further elaborates the EMMF implementation process, introducing timing and frequency considerations, and additional guidance regarding roles and responsibilities for the implementation of the environmental mitigation strategies presented in Table 6.

[45] Personal communication with Peter Cotty, USDA, 10 July, 2014.

Table 7: Timing and Frequency Considerations and Roles and Responsibilities

LIFECYCLE PHASE	ENVIRONMENTAL MITIGATION STRATEGY	TIMING AND FREQUENCY OF IMPLEMENTATION OF ENV. MITIGATION STRATEGY	ROLES AND RESPONSIBILITIES IN IMPLEMENTATION OF ENV. MITIGATION STRATEGY
1. Bio-control Research	Bio-control research (e.g., strain identification and isolation) is not covered by this PEA.	Bio-control research (e.g., strain identification and isolation) is not covered by this PEA.	Bio-control research (e.g., strain identification and isolation) is not covered by this PEA.
2. Awareness Raising and Demand Creation	Awareness raising must underscore that aflasafe is not a quick-fix solution; instead, aflasafe should be promoted as one tool within a set of resources for the control of aflatoxins.	Awareness raising should begin at project outset, and persist throughout life-of-project.	Awareness raising will be a joint responsibility between the IP and relevant government agencies. Ministry of Agriculture Extension Services, Agronomic Universities, and Research Institutes are primary agents of agricultural extension services and should be engaged in these efforts.
	Expectations must be set regarding the efficacy of aflasafe and the parameters for use to maximize results (e.g., aflasafe does not necessarily make food safe immediately and application may be required over multiple planting seasons)	Efforts to promote certification, labeling, and branding processes should likewise be initiated early at the policy level. The evolution of these processes will likely take years before fruition, and should be routinely revisited (e.g., every 3-6 months).	IP must coordinate with relevant government officials (e.g., MoA, bureau of standards, pesticide registration boards) in efforts to establish formal certification, labeling, and branding processes. Private-sector actors along the value chain (e.g., agro-retailers, potential lab certification services, end users and other downstream consumers) are to be consulted in planning and evaluating viable alternatives.
	As the product popularizes, certification/ labeling/branding requirements will be needed to legitimize the use of the product via market differentiation and, eventually, establish a product premium.	The timeline for development and formalization of certification/labeling/ branding processes will vary by country. It is unlikely that such processes will be developed sooner than 2-3 years following introduction of aflasafe, though in reality, reliable process development may take much longer.	The IP must ensure that aflasafe is understood as part of a broader suite of options for the control of aflatoxins and must advocate for agricultural GMPs as well. EMMPs must be developed for these GMPs.
3. Registration of aflasafe	Adherence to the host-country (and any regional) bio-pesticide	In some countries registration may be in	The IP, working in conjunction with the host-country

LIFECYCLE PHASE	ENVIRONMENTAL MITIGATION STRATEGY	TIMING AND FREQUENCY OF IMPLEMENTATION OF ENV. MITIGATION STRATEGY	ROLES AND RESPONSIBILITIES IN IMPLEMENTATION OF ENV. MITIGATION STRATEGY
	registration processes is required to ensure registration of a safe product in a manner which has little to no adverse environmental impact.	stages, with a provisional registration period followed by a final, full registration. While the registration process may be a one-time endeavor, more often registration is for a period of 3-5 years, with re-registration required. Ultimately, the specific process will be subject to host-country and regional registration procedures (including fees and periodic re-registration, where required).	pesticide registration board, will be responsible for providing the full dossier and support (as appropriate) to in-country field testing efforts. All necessary registration and permitting fee requirements will be met.
4. Establishment of Manufacturing	The construction of manufacturing facilities must comply with all applicable host-country review and certification/approval requirements. Where such host-country review processes do not exist, site selection of manufacturing facility must at minimum account for target beneficiaries (i.e. smallholder farmers in areas with highest recorded levels of aflatoxins and drivers of demand such as poultry-farmers or others with a vested economic interest in the gains realized from aflasafe manufacture and use).	Site screening should be conducted routinely, at multiple locations, in advance of any final siting decisions. If any host-country permitting requirements exist, screening timing and frequency should conform to those requirements.	The IP will be responsible for preparation of all host-country environmental or civic documentation, which may include application for permits or preparation of a site-specific Environmental Assessment for the construction of the manufacturing facility. The AOR/COR will be responsible for ensuring these are developed and the REO/A or MEO must review and approve this country-level documentation. Where host-country permitting or environmental assessment is not required, the IP is responsible for, at minimum, ensuring the all candidate sites for manufacturing facility are screened for any potential risks to the local community or environment. It is not anticipated that the construction of specific manufacturing facilities will trigger preparation of an

LIFECYCLE PHASE	ENVIRONMENTAL MITIGATION STRATEGY	TIMING AND FREQUENCY OF IMPLEMENTATION OF ENV. MITIGATION STRATEGY	ROLES AND RESPONSIBILITIES IN IMPLEMENTATION OF ENV. MITIGATION STRATEGY
			Environmental Assessment in order to comply with USAID Reg. 216 procedures; instead the IP will be expected to prepare an EMMP governing construction of these facilities. The REO/A or MEO must review and approve the EMMP, as well as all pre-construction site-screening documentation.
	The manufacturing facility must comply with basic worker safety and environmental controls, including air handling equipment, and wastewater and solid waste management. These elements must be assured during pre-construction planning.	During planning and design of manufacturing facilities, air, water, and solid waste quality management infrastructure must be accounted for and included in manufacturing facility specifications. This is a one-time, up-front requirement.	The IP, in coordination with AOR/COR and MEO or REO/A is responsible for ensuring sound design and construction of the manufacturing facility.
5. Manufacturing Processes and aflasafe Production	Adequate QA/QC mechanisms will need to be instituted as part of the manufacturing process to ensure the availability of aflasafe that is effective and performs to expectations. To ensure this, each aflasafe manufacturing facility must prepare, maintain, and regularly update a (SOP document that addresses all operational aspects of the facility, including, but not limited to, maintenance and security procedures and scheduling, and all technical procedural steps to be taken during the production of aflasafe. Each batch of aflasafe is to be tracked for raw materials used (including source, cost, and Lot no.s, where applicable), process steps implemented, and production volumes. Additionally, the manufacturing	The manufacturing facility is to be inspected routinely (e.g., weekly or monthly) throughout facility operation to assure that machinery and production equipment is operating as specified.	The IP is responsible for regular inspections of the manufacturing facility assuring quality and efficacy of equipment. The AOR/COR, and REO/A or MEO should perform site visits semi-annually. The IP will also be responsible for preparation of the SOPs for the manufacturing facilities. The AOR/COR and REO/A or MEO must approve all SOPs.

LIFECYCLE PHASE	ENVIRONMENTAL MITIGATION STRATEGY	TIMING AND FREQUENCY OF IMPLEMENTATION OF ENV. MITIGATION STRATEGY	ROLES AND RESPONSIBILITIES IN IMPLEMENTATION OF ENV. MITIGATION STRATEGY
	facility should have an on-site laboratory or capacity to assess the quality of the aflasafe upon production, prior to packaging and distribution.		
	Basic, low-cost facility and process controls will need to be in place to contain aflasafe and its active ingredients, preventing dispersal or contamination of the local environment or the potential for adverse impacts on nearby sensitive or immunocompromised populations.	With each batch of aflasafe produced, quality should be verified at a sufficiently equipped laboratory.	The IP is responsible for ensuring manufacturing facilities have the equipment necessary to evaluate product quality and that manufacturers incorporate product quality testing in their operations. The IP will also be responsible for ensuring that there is quality inspection of all packaging.
6. Post-Production Storage and Distribution	Finished product must be channeled through reliable and trustworthy input and agro-supply dealer networks and made available to consumers at a competitive price.	Oversight of post-production storage and distribution will be necessary throughout life-of-project. This will be most effectively done via visits to agro-retailers or agricultural extension agents that are	The IP, MEO or REO/A, and AOR/COR should all be active participants in site visits to agro-retailers or extension agents distributing aflasafe. These site visits should not always be joint (though at times joint visits may be most appropriate and economical)

LIFECYCLE PHASE	ENVIRONMENTAL MITIGATION STRATEGY	TIMING AND FREQUENCY OF IMPLEMENTATION OF ENV. MITIGATION STRATEGY	ROLES AND RESPONSIBILITIES IN IMPLEMENTATION OF ENV. MITIGATION STRATEGY
	Existing distribution channels, such as Ministry of Agriculture Extension Services or other agricultural support mechanisms, should be leveraged where possible to reduce costs and potential inefficiencies in distribution. Further, regular visits to agro-retailers are required to ensure proper storage, packaging, and re-sale of the product	predominant drivers of aflasafe sale and/or distribution. Such visits should occur quarterly during the first year of production, and at least semi-annually thereafter.	and should focus on the efficacy of packaging and labeling, efforts to market or advertise the product, and the quality of instruction provided at time of sale or distribution.
7. Use of aflasafe	Training/demonstrations on proper application, handling, storage, and disposal of aflasafe should be incorporated into aflasafe manufacture and use activities. Ministry of agriculture extension services, or like agricultural support mechanisms, should be beneficiaries of awareness-raising and capacity building efforts on aflatoxins and aflasafe. Utilize a "training the trainers" approach to empower downstream training on proper use of aflasafe.	Evaluation of the need for awareness-raising should be conducted as part of project implementation. Based on that evaluation, a training and capacity building program should be developed, informed as appropriate by guidance provided in Section 8 of this PEA. The training and capacity building program should establish the frequency of awareness and capacity building efforts. Demonstrations should be built into the training and capacity program, and additional details are provided in Section 8. As noted above, the frequency of demonstration plots will be established in the training and capacity building program.	The IP will be responsible for conducting initial evaluation of the need for awareness raising and capacity building. The IP will then be responsible for development of a training and capacity building program. The REO/A and MEO will be responsible for review and approval of the training and capacity building curricula.
	Incorporate training/demonstrations on proper application, handling, storage, and disposal of aflasafe into aflasafe manufacture and use activities.	Inventory management systems may be informal, but should be integrated upon receipt of product at all appropriate stops along the value chain. Inventory management should be an	The REO/A, MEO, and AOR/COR should review and support IP development and integration of inventory management systems across the value chain. While no formal approval for the system

LIFECYCLE PHASE	ENVIRONMENTAL MITIGATION STRATEGY	TIMING AND FREQUENCY OF IMPLEMENTATION OF ENV. MITIGATION STRATEGY	ROLES AND RESPONSIBILITIES IN IMPLEMENTATION OF ENV. MITIGATION STRATEGY
	Establish inventory management systems to help identify storage issues and track potential expiration of stored products. As products near expiration, if unlikely to be used at current location, re-distribution should be explored.	ongoing priority, with weekly or, at minimum, monthly reviews of stocked aflasafe.	is needed, implementation of an inventory management system is required.
8. Food Safety Surveillance	Because aflasafe has been shown to have an "area effect"[46] (meaning that it reduces levels of aflatoxins in the fields applied as well as adjacent and area fields), establish life-of-project monitoring systems to focus on comparisons of the levels of aflatoxins in treated areas versus those in untreated areas. The monitoring parameters are further developed in Section 7.3 of this PEA.	Long-term monitoring efforts should entail, at minimum, seasonal sampling of both treated and untreated 'areas' to capture the efficacy and "area effect" of aflasafe use. Sampling should begin prior to aflasafe production and use, and continue throughout life-of-project.	The IP will be responsible for ensuring that seasonal sampling is conducted. Efforts should focus on randomized samples from treated areas. REO/A and/or MEOs and AOR/COR should participate in at least one sampling event each year. The IP will be responsible for synthesis and reporting of findings from sampling.
	Use epidemiological surveys to track prevalence of diseases linked to acute and chronic exposure to aflatoxins throughout life-of-project. The monitoring parameters are further developed in Section 7.3 of this PEA.	Conduct epidemiological surveys on an annual basis to track any potential trends indicating reduced exposure to aflatoxins.	The IP will be responsible for coordinating with host-country ministry of health officials to determine viability, and (if viable) oversee implementation of epidemiological surveys. USAID AOR/COR should be engaged in, and provide oversight for this process.

Through adherence to the EMMF implementation process, potential human health and environmental impacts from aflasafe manufacture and use can be limited to an acceptable level.

Section 7.3 elaborates the monitoring parameters for effective oversight of environmental management of aflasafe manufacture and use.

46 Personal communication with Peter Cotty, USDA; 10 July, 2014, via teleconference.

3. LIFE-OF-PROJECT MONITORING OF ENVIRONMENTAL MANAGEMENT AND EFFICACY OF AFLASAFE

There are two key components to monitoring for environmental management of aflasafe: **Monitoring IP adherence to, and overall efficacy of, environmental safeguards and monitoring overall efficacy of aflasafe manufacture and use**. These are described further below.

MONITORING IP ADHERENCE TO, AND OVERALL EFFICACY OF, ENVIRONMENTAL SAFEGUARDS.

As detailed in section 7.2, the AOR/COR, REO/A, and (where applicable) MEO will be responsible for routine site visits, which shall examine those elements of the EMMF implementation that are successful, and those areas that require additional attention beyond observed practices. The IP shall likewise provide briefings to the AOR/COR, REO/A and MEO regarding the overall status of EMMF implementation. The findings from site visits and IP briefings should inform environmental reporting for the proposed aflasafe manufacture and use activities.

MONITORING OVERALL EFFICACY OF AFLASAFE MANUFACTURE AND USE

Monitoring the efficacy of aflasafe is important for a variety of reasons. First and foremost, it is essential to verify that funding is yielding the desired improvements in food safety and public health. Where such improvements are not realized, it is equally important to know that as early as possible in order to make adjustments in program implementation or reallocate project resources.

With this in mind, Food Safety Surveillance, as introduced in Section 7.1 as one of the lifecycle phases for aflasafe manufacture and use, is further expanded in Tables 6 and 7 in Section 7.2. Food Safety Surveillance must be done in a manner that effectively tracks positive impacts expected from the manufacture and use of aflasafe (e.g., reduced levels of aflatoxins in treated areas) against an unaffected baseline. For this reason, the PEA proposes two Food Safety Surveillance strategies. These strategies should be considered and evaluated by the IP, with relevant host-country and regional officials. As noted in the General EMMF Implementation Requirements, any formal modification to the EMMF Implementation process will require REO/A and AFR BEO approval.

The two Food Safety Surveillance strategies recommended by this PEA are: **(1) Randomized sampling of areas treated with aflasafe (treated areas) and areas that have not been treated with aflasafe (untreated areas)** and; (**2) epidemiological studies evaluating the prevalence of human health concerns related to aflatoxins.** These are developed below.

RANDOMIZED SAMPLING OF AREAS TREATED WITH AFLASAFE (TREATED AREAS) AND AREAS THAT HAVE NOT BEEN TREATED WITH AFLASAFE (UNTREATED AREAS)

Section 5 of this PEA provides useful overview of this issue in response to the seventh issue of concern (see Table 4):

> *Certain aflasafe proponents suggest that the cost of analysis is almost prohibitively expensive and that, considering the product's demonstrated efficacy to date, resources are more wisely spent on aflasafe procurement and promoting widespread use. Existing sampling practices are also especially problematic: by one account taking a single sample (e.g., a single ear of maize, or even selected kernels) and dividing into multiple segments for independent evaluation at different laboratories can result in as many disparate results as segments created. Much of this variability stems from the growth of A. flavus, which will cluster in some parts of the sample and be sparse, or non-existent in others.*
>
> *Even with the development and/or introduction of a technically sound protocol and corresponding methods, capacity limitations at the local or national levels may hamper effective assessment of aflasafe-*

treated produce. A dearth of adequately trained personnel or lack of laboratory consumables or facilities could easily impair the efficacy of any produce testing regime.

USDA is currently developing a statistically sound sampling protocol to evaluate the safety (i.e., concentrations of regulated aflatoxins) of maize prior to export. This sampling protocol will draw from aggregation facilities to determine whether maize for export is suitable for trade.[47] While such sampling protocol may not directly align with aflasafe manufacture and use, it could be a useful data point in evaluating whether food safety is improving in areas, or countries, implementing aflasafe manufacture and use activities. Ultimately, the belief is that random samples of sufficient scale in treated and untreated areas should provide indicative information about the positive impacts emanating from manufacture and use of aflasafe. This approach addresses the concern about the cost-prohibitive nature of farm-by-farm sampling, while still recognizing food safety concerns at the smallholder farm level. The trade-focused approach being developed by USDA is likely to give less attention to smallholder farmers, however, it should be considered the preeminent approach to assessing the safety of produce intended for export.

EPIDEMIOLOGICAL STUDIES EVALUATING THE PREVALENCE OF HUMAN HEALTH CONCERNS RELATED TO AFLATOXINS

Regarding the second strategy, there is a well established history of the adverse human health impacts associated with both acute and chronic exposure to aflatoxins. Though project implementation may not be of sufficient length to fully track public health improvements resulting from reduced chronic exposure to aflatoxins, at a minimum, efforts to develop and routinize epidemiological studies—through coordination with Ministry of Public Health officials, for example—can establish important baselines in helping USAID and participant countries track this public health issue during and subsequent to project implementation. Public health monitoring would be most effective after large-scale use of aflasafe has been implemented and control of aflatoxins has been established. This may be beyond the lifecycle of the work to which this PEA applies. Alternatively, evaluation of the reduction in aflatoxins in food may be used as a measure of the improvement to human health.

[47] Personal communication with Jason Sandahl, USDA, 22 July, 2014

SECTION 8: ENVIRONMENTAL MANAGEMENT AND TRAINING

Each point or phase in the aflasafe product lifecycle addressed in Section 7 will require a thoughtful and deliberate approach to the mitigation and monitoring of potential adverse environmental impacts. A certain number of these mitigation and monitoring efforts warrant specialized skills or capacity building; others may suffice with a brief training or orientation. In any case, effective environmental mitigation and monitoring is predicated on the availability of a well-equipped pool of qualified individuals prepared to fulfill the various criteria.

The proponents of aflasafe will need to integrate a training and capacity building strategy as part of broader commercialization efforts. The development of training and capacity building objectives should include those related to environmental mitigation and monitoring. To facilitate this planning and integration, this section of the PEA outlines likely training and capacity building needs by aflasafe lifecycle phase. A recommended time frame is also provided for each phase to help prioritize investment in training and capacity building activities.

PHASE 1: BIO-CONTROL RESEARCH

CAPACITY BUILDING AND TRAINING NEEDS

- While bio-control research for aflasafe development is outside the scope of this PEA, USAID has already invested in efforts to build capacity among research institutions and facilities capable of supporting the strain identification and isolation processes undertaken during this phase of product development.

TIME FRAME

- As demonstrated by aflasafe product development efforts already underway, capacity building in this area requires significant investment in time and resources. Commencing investment in bio-control research capacity 2 – 3 years prior to anticipated aflasafe manufacture and use is not unrealistic.

PHASE 2: AWARENESS RAISING AND DEMAND CREATION

CAPACITY BUILDING AND TRAINING NEEDS

- Assistance in capacity building for government officials and leaders in agriculture, (bio)pesticide production and use, and public health in order to develop a joint strategy for the control of aflatoxins in the country.
- Developing the capacity to launch “awareness creation” programs that target government institutions and the producers and consumers of crops affected by aflatoxins. Awareness programs should emphasize the dangers of contamination caused by aflatoxins and the likely positive impacts of adopting aflasafe technology. This can be achieved through the ongoing publication of scientific and market-oriented articles, flyers, etc., crop and/or product demonstrations, and media outreach, including farmer testimonials on local broadcast radio. USAID should be prepared to support the translation of marketing and communications materials where needed.

TIME FRAME

- High-level efforts to address these capacity needs are already underway in several countries (e.g., Kenya, Tanzania, Nigeria). However, these efforts should be ramped up as aflasafe-related efforts gain momentum and to ensure that stakeholders are reached prior to commercial availability.

PHASE 3: AFLASAFE REGISTRATION

CAPACITY BUILDING AND TRAINING NEEDS

- The regulatory entities that assess and register pesticides at either the country level (e.g., PCPB in Kenya, or TPRI in Tanzania) or the regional level (e.g., EAC, SADC, etc.) will require the technical expertise, policies, and procedures to effectively evaluate and qualify bio-control technologies such as aflasafe. These entities will also require access to the tools and resources needed to perform their essential functions, such as adequate laboratory facilities, consumables, and peer-reviewed literature.

TIME FRAME

- Adequate capacity in this area should be in place prior to seeking product registration at the country or regional level.

PHASE 4: ESTABLISHING MANUFACTURING

CAPACITY BUILDING AND TRAINING NEEDS

- Staff and personnel from contracted institutions (e.g., private architectural or construction firms) must be able to meet relevant engineering and safety requirements associated with establishment of the physical manufacturing plants. This includes but is not necessarily limited to provision of, and training on, the manufacturing facilities' SOPs and EMMPs for plant construction.

TIME FRAME

- Contracted entities can be pre-qualified as possessing knowledgeable and experienced staff. This process can commence prior to solicitation and/or procurement. Adherence to engineering and safety criteria must be followed from design and planning stage through to post-construction.

PHASE 5: MANUFACTURING PROCESSES/AFLASAFE PRODUCTION

CAPACITY BUILDING AND TRAINING NEEDS

- Technical assistance for agricultural research institutions, agronomic universities, food safety institutes, and/or standards bureaus to construct and equip a testing laboratory that can support QA/QC of manufactured aflasafe for the manufacturing facilities being established and operated.
- Training of microbiological laboratory technicians in use of analytical methods, instrumentation and equipment.
- Technicians responsible for workflow and the manufacturing process will be required to adhere to standard operating policies and procedures, including worker safety protocols.
- Individual workers must be trained in and adhere to occupational health and safety requirements, such as the use of PPE, response protocols (e.g., for spills, fire, etc.), and any required bio-monitoring efforts.
- Plant managers and/or production supervisors must ensure implementation of the facility's environmental management plan and ensure compliance with applicable standards and regulations.

TIME FRAME

- Training and capacity building in this area should coincide with planning and construction of the manufacturing facility. This timing will enable employment of a trained, well-qualified workforce at the time the plant is completed and aflasafe production comes online.

PHASE 6: POST-PRODUCTION STORAGE AND DISTRIBUTION

CAPACITY BUILDING AND TRAINING NEEDS

- Training of agricultural input wholesalers, distributors and retailers in handling, storage, distribution, and safe disposal protocols.
- Training in inventory management and strategies to re-distribute stock prior to expiration to maximize the availability and efficacy of aflasafe.

TIME FRAME

- Training and capacity building in this area should coincide with the commencement of commercial aflasafe production and once protocols for product handling, storage, and disposal have been established by the registrant and/or manufacturer (consistent with the product registration requirements).

PHASE 7: AFLASAFE USE

CAPACITY BUILDING AND TRAINING NEEDS

- Training and skills development for NGOs and agricultural extension agents involved in agricultural training and extension programs for farmers to understand safe use and handling of waste materials after application.
- Training of farmers and producers (or producer groups) of crops affected by aflatoxins and the recommended safe storage and use of aflasafe, as well as handling and disposal of waste materials following use.
- Training of farmers and producers (or producer groups) on complementary harvesting and post-harvest GMPs that reduce aflatoxins (such as those currently promoted by the aflaSTOP project, including good harvesting, post-harvest handling and storage management technologies) to complement the use of aflasafe.
- Training of aggregators, processors, transporters and produce/grain warehouse staff in transporting, handling and storage of aflasafe-treated produce in warehouses.

TIME FRAME

- This process should commence concurrent with the field-testing phase, before the product is commercially available.

PHASE 8: FOOD SAFETY AND SURVEILLANCE

CAPACITY BUILDING AND TRAINING NEEDS

- Training in the development of appropriate sanitary and phyto-sanitary standards and sampling and analytical methods to ensure effective surveillance (and possible regulation) of aflasafe-treated produce.
- Supporting technical training of relevant environmental or health inspectors at cognizant agencies in the implementation of the sampling protocols and/or analytical methods needed to monitor produce (e.g., institutional capacity building for ministries of health and agriculture, pesticide registration boards, agricultural and/or pesticide research institutes, etc. to ensure uniformity and consistency of results).
- Provision of appropriate analytical equipment and supplies to private- and public-sector laboratories.

TIME FRAME

- These capabilities should be developed in advance of the commercial production and distribution of aflasafe.

ATTACHMENT A: LIST OF PREPARERS

[redacted]; **Team Leader**. [redacted] is an international development professional specializing in environmental impact assessment and natural resource management. A trained planner, [redacted] is highly proficient in USAID environmental procedures and the integration of good management practices, particularly in the area of agriculture and food security. He has research and field team leadership experience, and has implemented radio-based outreach to promote water and soil conservation programs. He is also an experienced trainer, having designed and facilitated multi-day workshops in Asia, and throughout Africa. His work in Africa goes back nearly 20 years, to his time as a Peace Corps Volunteer in Rep. of Congo. He has additional work experience in Egypt, Ethiopia, Kenya, Liberia, Madagascar, Nigeria, Senegal, Sierra Leone and Zimbabwe, most of it supporting a range of USAID development objectives in the region. [redacted] is currently a Senior Associate at The Cadmus Group, Inc., where he oversees and implements a variety of contracts and projects on behalf of the company's international development practice. He holds a B.A. in history from the University of Missouri-Columbia and a M.A. in Urban and Environmental Policy and Planning from Tufts University.

[redacted]**; Risk Assessor**. [redacted] is a risk assessor specializing in chemical fate and transport in the environment, human health and ecological risk assessment, analytical methods, and pesticides. For the past two years, he has been preparing and providing critical review and revision to Pesticide Evaluation Reports and Safer Use Action Plans (PERSUAPs) for USAID-supported projects across sub-Saharan Africa, including Benin, Burkina Faso, Cote d'Ivoire, Ethiopia, Ghana, Kenya, Liberia, Mali, and Togo. Originally trained as an organic chemist, he spent more than seven years in the Pharmaceutical industry prior to becoming an environmental scientist. He holds a B.S. in Chemistry from Worcester Polytechnic Institute and a M.S. in Civil and Environmental Engineering from Tufts University.

[redacted]**; Field Agronomist.** [redacted] is an agronomist and natural resource and environmental management specialist with 34 years of post-doctoral specialization in environmentally sound design and management training, program design and management, export development for fresh horticultural produce, and value chain analysis and development. He has also worked with gender mainstreaming, institutional capacity assessment and strengthening, curriculum and training materials development, and the development of monitoring and evaluation systems. [redacted] a commercial farmer, has been engaged in the establishment and management of commercial farms and provided a range of consultancy services to local and international organizations, gold mining companies and NGOs. He has helped to conduct USAID-funded environmental assessments and provided training in environmentally sound design including USAID's Reg. 16 compliance work in Ghana, Ethiopia, Niger, Burkina Faso, Sierra Leone, Rwanda, Tanzania and Uganda. [redacted] has extensive experience working with teams in the design, management, and evaluation of natural resources and environmental activities.

[redacted]**; Food Safety and Production Specialist.** [redacted] is an international development professional with expertise and experience in regulatory environmental compliance. Her educational background is in food technology, environmental risk assessment and business administration. [redacted] work experience includes ensuring environmental compliance of international projects, conducting environmental impact assessments, developing environmental plans and reports, and integrating environmental compliance planning into new project design. She developed, implemented and managed technical assistance donor-funded projects in the US and overseas. She also provided technical leadership to develop Environmental Management Systems (EMS) and worked to establish environmental compliance policies, procedures and knowledge sharing systems throughout the headquarters and field offices. [redacted] has also designed and delivered training on environmental compliance. Her regional experience includes Eastern Europe and Central Asia, Africa, the Middle East and Latin America.

[redacted] **Plant Geneticist.** [redacted] is a botanist by profession specializing in genetics. A trained plant biotechnologist, [redacted] has wide experience in tissue culture, transformation and environmental risk assessment of genetically modified organisms. He has research and team experience, including having participated in the International Project on GMO Environmental Risk Assessment Methodologies (GMO ERA) that was involved in drafting of guidelines for use in environmental risk assessment of Bt maize and cotton in Kenya, Brazil and Vietnam. He was also the Assistant Kenyan Coordinator of the Capacity Building for Biosafety and Ecological Impact Assessment of Transgenic Plants in East Africa (Biosafe Train) Program that was aimed at training postgraduate students in environmental risk assessment. The program also involved conducting workshops on the safe use of biotechnology by relevant government agencies and other stakeholders in Kenya, Uganda and Tanzania. [redacted], with 21 years' experience in biotechnology, is currently a Senior Lecturer at the University of Nairobi, School of Biological Sciences where he is involved in teaching and research. He holds a B.A. in Education (Science) from Kenyatta University, a M.S. in Genetics and a Ph.D in Botany (Genetics) both from the University of Nairobi.

[redacted]**; Environmental Impact Assessment Specialist.** [redacted] is an international development professional with specializations in environmental impact assessment and regulatory environmental compliance. With an educational background in international environmental policy and political economy, [redacted] work experience includes technical review and evaluation of USAID environmental compliance documentation and implementation. [redacted] has provided oversight and support as an environmental impact assessment specialist on two prior USAID Programmatic Environmental Assessments, one evaluating promotion of agribusinesses to improve agricultural efficiency, the other reviewing rehabilitation of rural feeder roads. His international work experience extends seven years, with experience in Costa Rica, Ecuador, Chile, Liberia, Ghana, Tanzania, Kenya, Burundi, Republic of Georgia, and Kosovo. [redacted] is currently a Senior Analyst at The Cadmus Group, Inc., where he supports oversight and implementation of international environmental management contracts and projects on behalf of the company's international practice. He holds a B.A. in political philosophy from the University of Wisconsin-Madison and a M.A. in Law and Diplomacy from the Fletcher School at Tufts University.

ATTACHMENT B: STAKEHOLDERS CONSULTED

DAY	PARTICIPANTS	PEA TEAM	LOCATION
29 May 2014	[redacted], Professor of Medical Microbiology and Immunology and Bacteriology University of Wisconsin, Madison	[redacted]	US (via teleconference)
5 June 2014	[redacted], Senior Food Security & Nutrition Advisor, IITA [redacted], Plant Pathologist for East/Central Africa, IITA	Field Team B**	IITA East Africa Regional Hub Dar es Salaam, Tanzania
	[redacted], Director, Directorate of Environmental Compliance and Enforcement	Field Team B	National Environment Management Council (NEMC) Dar es Salaam, Tanzania
8 June 2014	N/A	Field Team A*	Nairobi, Kenya
9 June 2014	N/A	Field Team A	Fairview Hotel Nairobi, Kenya
	[redacted], Executive Committee Member Kenya Ministry of Agriculture, Livestock and Food Security	Field Team A	Nairobi, Kenya (via teleconference)
	[redacted], East Africa Aflasafe Coordinator International Institute of Tropical Agriculture (IITA)	Field Team A	Nairobi, Kenya
	[redacted], USAID/East Africa	Field Team A	Café Four, Warwick Center Nairobi, Kenya
	[redacted], Senior Program Manager – Food Safety, TSCBD, with the U.S. Department of Agriculture and [redacted] Senior Advisor – Trade & Scientific Capacity Building with the U.S. Department of Agriculture.	[redacted]	US (via teleconference)
	[redacted], Chief Research Officer, Tropical Pesticides Research Institute (TPRI) [redacted], E.E, Principal Research Scientist, Registrar of Pesticides, TPRI	Field Team B	TPRI Main Offices Arusha, Tanzania
	[redacted], Farming Systems Agronomist, Africa RISING East & Southern Africa Region Project	Field Team B	Africa Rising Project Office Arusha, Tanzania
10 June 2014	[redacted] Principal Research Officer, Kenya Medical Research Institute	Field Team A	Nairobi, Kenya

	(KEMRI)		
	[redacted], General Manager, Phytosanitary Services & [redacted], Plant Inspector, Kenya Plant Health Inspectorate Service (KEPHIS)	Field Team A	KEPHIS Headquarters Karen, Nairobi, Kenya
	[redacted], Africa RISING, IITA [redacted] Food Safety Specialist, Africa RISING, IITA [redacted], Post-Harvest Specialist, Africa RISING, IITA	Field Team B	Field site visits – maize fields where sampling for analysis of the levels of aflatoxin was ongoing. Tanzania
11 June 2014	[redacted] Centre Director, KARI Katumani Kenya Agricultural Research Institute (KARI)	Field Team A	KARI-Katumani agricultural research station
	[redacted], USAID/Kenya Kaves	Field Team A	
	[redacted], Director – IITA Eastern Africa Hub	Field Team B	IITA East Africa Regional Hub Dar es Salaam, Tanzania
	[redacted] Ministry of Agriculture, Food Security, and Cooperatives	Field Team B	Kanduchi Hotel Dar es Salaam, Tanzania
	[redacted] Head of the National Steering Committee on Mycotoxins, Dean of Agriculture at the school of Computational and communication Science and Engineering (COCSE), The Nelson Mandela African Institution of Science and Technology (NM-AIST)	Field Team B	Kanduchi Hotel Dar es Salaam, Tanzania
	[redacted] Technical Officer, PACA, African Union Commission	Field Team B	Kanduchi Hotel Dar es Salaam, Tanzania
12 June 2014	Local Stakeholders at Field Site Visit #2	Field Team A	Kiambu, Kenya
	[redacted], Acting Chief Executive Kenya Pest Control Products Board (PCPB)	Field Team A	PCPB Headquarters Nairobi, Kenya
13 June 2014	[redacted] Director, Public Health &	Field Team A	Afya House, 4th Floor, office 417

	[redacted] Sr. Public Health Officer Kenya Ministry of Health		Nairobi, Kenya
	[redacted], Director, Crop Protection Services & [redacted], Head Crop, Post Harvest Officer, Crop Protection Services Kenya Ministry of Agriculture, Livestock and Fisheries, Department of Veterinary Services	Field Team B	KARI, National Agriculture Research Laboratories (NARL), off Waiyaki Way Nairobi, Kenya
	[redacted], Assistant Director, Horticulture and Industrial Crops Kenya Agricultural Research Institute (KARI)	Field Team B	KARI, National Agriculture Research Laboratories (NARL), off Waiyaki Way Nairobi, Kenya
	[redacted] Chief Compliance Officer, Department of Compliance and Enforcement, Kenya National Environmental Management Authority (NEMA)	Field Team A	NEMA Offices, South C Nairobi, Kenya
	USAID/East Africa	Full PEA Team***	Café Four, Warwick Center Nairobi, Kenya
16 June 2014	[redacted] & [redacted], Burundi Bureau of Standards (BBN)	[redacted]	Bujumbura, Burundi
	[redacted], Food and Agriculture Organization (FAO)		Bujumbura, Burundi
	[redacted], Plant Protection at Ministry of Agriculture and Livestock		Bujumbura, Burundi
	[redacted] Environmental Officer, USAID/Uganda		Kampala, Uganda
	[redacted], Professor and Head, Department of Food Technology and Nutrition, Makerere University		Kampala, Uganda
	[redacted], Chief of Party (COP), USAID/Uganda, Feed- the-Future, Agricultural Inputs project		Kampala, Uganda
17 June 2014	[redacted], Jonathan Hatungimana & Alphonse Fofo, INECN		Bujumbura, Burundi
	[redacted], CNTA		Bujumbura, Burundi
	[redacted] & [redacted], ISABU, Land Management and Cropping		Bujumbura, Burundi

	Systems		
	Yves Uwarugira, Ministry of Environment	[redacted]	Bujumbura, Burundi
	[redacted] (MSc student) currently doing a project on "*Aspergillus* species and aflatoxin contamination in pre- and post-harvest peanuts in Baringo, Elgeyo-Marakwet and Meru Counties in Kenya" under the supervision of [redacted] University of Nairobi.		School of Biological Sciences, University of Nairobi Nairobi, Kenya
	[redacted] System Agronomist, Country Representative, IITA		Kampala, Uganda
	[redacted] Director, [redacted] Maize Breeder, Programme Leader, Cereals Research, [redacted] Research Officer, Cereals Programme, National Crop Resources Research Institute (NaCRRI), National Agricultural Research Organization (NARO)		Namulonge, Uganda
18 June 2014	[redacted] & [redacted] Ministry of Agriculture		Bujumbura, Burundi
	[redacted] & [redacted] IITA Burundi		Bujumbura, Burundi
	[redacted] Chief of Party (COP), CATALIST-Uganda project implemented by the International Fertilizer Development Center (IFDC) supported by the Netherlands Ministry of Foreign Affairs through its embassy in Uganda		Kampala, Uganda
19 June 2014	[redacted] Commissioner for Crop Inspection and Certification & [redacted], Assistant Commissioner, Ministry of Agriculture, Animal Indutry and Fisheries (MAAIF)		Entebbe, Uganda
20 June 2014	[redacted] Part of the team that characterized Aspergillus flavus strains from Kenya at the University of Arizona		School of Biological Sciences, University of Nairobi Nairobi, Kenya
	[redacted] Ag. Head, Food and Agriculture Standards Division & [redacted] Principal Govt Analyst, Government Analytical Laboratories, Uganda National Bureau of Standards (UNBS)		Kampala, Uganda
27 June 2014	[redacted], Research Scientist, National Agricultural Biotechnology Centre, National Agricultural Research Laboratories		Kawanda, Uganda
30 June 2014	[redacted], Executive Director, & Patience Byaruhanga, Programme Director, Uganda National Agro-Dealers Association (UNADA)		Kampala, Uganda

1 July 2014	[redacted] Executive Director, The Grain Council of Uganda	[redacted]	Kampala, Uganda
2 July 2014	[redacted] Managing Director for Doreo Partners.		US (via teleconference)
	[redacted] Executive Director, National Environmental Management Authority (NEMA)		Kampala, Uganda
	[redacted] Director Economic Growth Team, [redacted], Policy and Enabling Environment Specialist, [redacted] Program Management Specialist, USAID/Uganda		Kampala, Uganda
10 July 2014	[redacted], Pathologist for IITA and Dr. Peter Cotty, Research Plant Pathologist for the U.S. Department of Agriculture		US (via teleconference)
5 Sept. 2014	[redacted], Research Assistant, North Carolina State University		US (via e-mail)

[redacted]

ATTACHMENT C: FINAL PEA WORKPLAN

Final Workplan: aflasafe™ Programmatic Environmental Assessment (PEA)

(GEMS II Activity AF06)

version date: 3 June, 2014

1. ABSTRACT

The **purpose** of this GEMS II activity is to prepare for USAID/East Africa:

1. **A 'core' Programmatic Environmental Assessment (PEA)** for the manufacture, field testing and distribution of aflasafe™, a commercial product based on atoxigenic strains of the fungus *Aspergillus flavus* (*A. flavus*). The core PEA will address at minimum the environmental issues of significant potential concern, as identified by the PEA Scoping Statement (also prepared by GEMS under the predecessor mechanism):

    a. Manufacture of aflasafe and engineering controls to ensure proper containment of the manufacturing process and the production of adequate quantities of aflasafe to ensure continued dominance by the preferred atoxigenic strains of *A. flavus*.

    b. The potential for toxigenic strains to re-appear if aflasafe application is stopped and the potential for recurring strains to change to more toxic strains and/or pathogenic strains.

    c. The availability of adequately robust sampling protocols and analytical procedures to ensure that treated produce is safe for human consumption.

    d. Potential adverse effects on sensitive human subpopulations (particularly those with compromised immune systems).

    e. Farmers and grain storage warehouse managers may not follow all relevant Good Management Practice (GMPs) to reduce risk of growth of the toxigenic strains of *A. flavus* during aflasafe storage and use in the field.

    f. The potential for toxigenic strains to compete with atoxigenic strains during aflasafe production.

    g. The ability for aflasafe to effectively out-compete and control growth of other aflatoxin-producing fungi, such as *A. parasiticus* and *A. tamarii*.

    h. The potential for fungal infestation by aflasafe, resulting in crops that are not toxic but are of limited or no nutritive value.

    i. The sheer scope of using aflasafe not only in the EAC, but employing the use in the EAC as a model for use of aflasafe in all of sub-Saharan Africa; and

2. **An East Africa-specific PEA Amendment** that will provide focused assessment and analysis and environmental management guidance for the manufacture, field testing and distribution of aflasafe specific to the following East African countries, consistent with discussions to date with USAID/East Africa: Kenya, Tanzania, Rwanda, Uganda, and Burundi.

    The sub-regional-specific PEA Amendment is expected to focus on issues such as discerning host-country registration processes against international standards, and considerations regarding the development of regional strains of *A. flavus*. Additional issues are expected to emerge through continued desk research, consultations, and field work in the East Africa sub-region.

The core PEA and East Africa PEA Amendment will conform to the requirements of 22 CFR 216 ("Reg. 216"), and will integrate current environmental best management practices promoted by USAID and Africa Bureau. The documents will significantly reduce the effort required by individual USAID operating units to develop Reg. 216 documentation for their planned aflasafe programming, or eliminate the need for operating-unit level documentation altogether. To the extent possible, the PEA Amendment will integrate common elements of relevant environmental assessment criteria among target countries in the East Africa region, thereby facilitating subsequent registration or environmental impact assessment (EIA) processes required by individual host countries.

2. AFLASAFE PEA TIMELINE AND DELIVERABLES SCHEDULE

PEA planning will begin 1 May 2014 and conclude with submission of the detailed PEA workplan. This will be followed by desk-based research and preparation, and then a field work component. Field work will be completed through the first several weeks of June 2014. Submission of both the draft core PEA and East Africa PEA Amendment will be on or before 25 July 2014; final documents will be completed on or before 8 September 2014, pending timely review and feedback from USAID.

Preliminary research and much of the technical analysis and writing for the core PEA and East Africa PEA Amendment will be done remotely, but in-country stakeholder consultations and data gathering will be conducted during the field work component. Field work, including data gathering and stakeholder consultation, will be undertaken in Kenya, Tanzania, Rwanda, Uganda, and Burundi. It is expected that in-person, in-country consultations with USAID/East Africa, as well as USAID bilateral missions, Environmental Protection Agencies (or equivalent), relevant Line Ministries, in-country laboratories, and/or other stakeholders and experts will be required during PEA field work.

The field work component will be completed by two short-term in-country teams comprised by GEMS project staff and Consultants with local technical assistance. Home office backstopping throughout will be provided by U.S.-based GEMS project staff.
The following tables summarize the aflasafe PEA timeline and schedule of deliverables.

Table 1: aflasafe PEA Timeline.

Dates	Activity/Phase
1 – 12 May	Prepare Detailed PEA Workplan: • Identify remaining data needs, including follow-up to the Scoping Statement recommendations. • Define priorities of PEA field work. • Identify other stakeholders to consult regarding the use of aflasafe. • Prepare and submit to USAID/East Africa a schedule for undertaking and completing the overall PEA, including detailed field work program.
13 – 30 May	Desk-based research and PEA preparation, including preparation of country-specific registration requirements.
2 – 20 June	Window for PEA field work; precise itinerary to be determined as part of detailed PEA workplan (see above)
23 June – 25 July	Prepare draft PEA document
28 July – 8 August	USAID review and comments on draft PEA
11 – 22 August	Prepare revised draft PEA
25 – 29 August	USAID review and comments on revised draft PEA

2 – 8 September	Prepare final PEA

Table 2: aflasafe PEA Deliverables and Deadlines (based on preliminary schedule above).

Deliverable	Deadline
Detailed PEA Workplan	12 May
Final field work itineraries and travel schedules	30 May
Draft PEA	25 July
Revised PEA*	22 August
Final PEA*	8 September

*timely submission of these deliverable is dependent on comments/feedback from USAID.

3. PLAN OF ACTIVITIES

This section provides detailed components for **Programmatic Environmental Assessment** activities.

PEA ACTIVITIES

PEA OBJECTIVES

As stated under 22 CFR 216.1(b), the purpose of the environmental assessment process is to:

(1) Ensure that the environmental consequences of the proposed project activities are identified and considered by USAID and the host country(ies) prior to a final decision to proceed and that appropriate environmental safeguards are adopted;

(2) Assist developing countries to strengthen their capabilities to appreciate and effectively evaluate the potential environmental effects of proposed development strategies and projects, and to select, implement and manage effective environmental programs;

(3) Identify impacts resulting from the proposed project upon the environment, including those aspects of the biosphere which are the common and cultural heritage of all mankind; and

(4) Define environmental limiting factors that constrain development and identify and carry out activities that assist in restoring the renewable resource base on which sustained development depends.

PEA ACTIVITIES

Upon USAID approval of this workplan the GEMS team will begin preparations for PEA field work. This includes:

1. Making logistical arrangements
2. Collection and analysis of data as will support PEA field work
3. Identify key stakeholders and primary locations of interest for PEA field site visits
4. Initiating and scheduling potential stakeholder meetings

Please refer to Section 2: *aflasafe PEA timeline and deliverables schedule*, for anticipated timing of field work and submission of final core PEA and East Africa PEA Amendment.

Tasks 1 – 10 below provide a detailed description of steps to be finalized through the PEA.

TASK 1. REVIEW EXISTING LITERATURE ON *A. FLAVUS* AND THE USE OF AFLASAFE AND LIKE PRODUCTS, INCLUDING OTHER ENVIRONMENTAL ASSESSMENTS (EAS) THAT MAY EVALUATE THE USE OF SUCH PRODUCTS.

STATUS: IN PROCESS

TASK 2. DEFINE RESEARCH METHODOLOGY FOR EVALUATING ENVIRONMENTAL AND SOCIAL IMPACTS
STATUS: IN PROCESS

The methodology for assessing the depth and breadth of potential environmental and social impacts—both as identified through the scoping process and those revealed through subsequent discussion with USAID stakeholders and among the PEA team—will seek to map these impacts to the cradle-to-grave process associated with proposed USAID support of aflasafe.
The overarching cradle-to-grave process is envisioned to include the following steps or phases:

A. Selection of crops for protection
B. aflasafe development
C. aflasafe field testing
D. aflasafe registration
E. Establishing aflasafe manufacture
F. Production/manufacturing process
G. aflasafe retail marketing
H. aflasafe application
I. aflasafe in combination with other practices combating aflatoxins
J. Crop quality, verification
K. Aggregation/Distribution/Storage
L. Marketing/Packaging/Consumption

Through a combination of desk study and field work, the PEA will evaluate how the environmental and social impacts map to the above steps and processes. Below are outlined the questions that will guide the assessment and inform this process mapping, for each of the environmental and social impacts as identified in the Scoping Statement and revealed through subsequent discourse.

Impact 1. Toxigenic strains of *A. flavus* may contaminate aflasafe and compete for growth during formulation, manufacture or use.

- Desk Study Approach
  - Contact IITA personnel, including but not limited to, Ranajit Bandyopadhyay and Charity Mutegi, for research that has been conducted in this area.
- Questions/Activities for Field Work
  - If possible, visit manufacturing facilities (e.g., warehouse-scale and/or modular), paying attention to measures being implemented to avoid cross-contamination (i.e., basic hygiene, sterilization equipment for culture media—autoclaves, chemical solutions, etc.). *Much of the manufacturing in East Africa is anticipated to be in modular facilities, at least for the near future.*
  - Ask field personnel (IITA) whether long-term monitoring for this potential issue is feasible and/or part of proposed activities.

Impact 2. The ability of aflasafe to effectively outcompete growth of other Aspergillus strains that may produce aflatoxins, such as *A. parasiticus* and *A. tamarii*.

- Desk Study Approach
  - Research available data (as possible) on natural ratios of *A. flavus* to *A. parasiticus* and *A. tamarii*.
- Questions/Activities for Field Work
  - If possible, visit IITA laboratories where speciation is being performed as initial phase of aflasafe development. Obtain any available data regarding issues with *A. parasiticus* and *A. tamarii* contaminating *A. flavus* cultures.
  - Ask field personnel (IITA) whether long-term monitoring for this potential issue is feasible and/or part of proposed activities.

Impact 3. The potential for atoxigenic strains of *A. flavus* in aflasafe to become pathogenic through recombination processes in the environment.

- Desk Study Approach
  - Evaluate scientific literature (while there may be limited evaluation specifically for aflasafe, the concept can be researched and documented to support/design potential future field monitoring).
- Questions/Activities for Field Work
  - Ask field personnel (IITA) whether long-term monitoring for this potential issue is feasible and/or part of proposed activities.

Impact 4. The potential for aflasafe application to cause fungal infestation of crops which, while not toxic, may result in crops that are of limited or no nutritional value?

- Desk Study Approach
  - Research past aflasafe application efforts to evaluate whether aflasafe has been observed to infest crops.
  - Research application efforts for like-products (particularly afla-guard™)
- Questions/Activities for Field Work
  - Observe aflasafe-treated maize to evaluate whether crop infestation is occurring.
  - Ask field personnel (IITA) whether long-term monitoring for this potential issue is feasible and/or part of proposed activities.

Impact 5. Adherence by farmers and grain storage warehouse managers to all relevant GMPs to reduce risk of the growth of the toxigenic strains of *A. flavus* during aflasafe storage and use in the field.

- Desk Study Approach
  - Identify and assess existing relevant Standard Operating Procedures (SOP) for the storage and use of aflasafe and assess any gaps or limitations.
- Questions/Activities for Field Work
  - Observe farmers applying aflasafe to fields.

Impact 6. What effect might localized modular manufacturing locations have on sensitive subpopulations, such as those with compromised immune systems (either as workers involved in the manufacturing process or as nearby residents)?

- Desk Study Approach
  - Research use of EPA-registered forms of *A. flavus* in Texas and Arizona to see if similar issues have been evaluated.
- Questions/Activities for Field Work
  - Meet with local and national public health officials to discuss concerns for public health.
  - Meet with local physician(s) to discuss potential health impacts.
  - Ask public health/medical personnel whether long-term monitoring for this potential issue is feasible and/or part of proposed activities.

Impact 7. Controlled manufacturing processes capable of producing adequate quantities of regionally-specific formulations of aflasafe to maintain required application frequency to ensure long-term crop protection.

- Desk Study Approach
  - Obtain updated information from IITA regarding number of proposed modular facilities in each country and whether any additional factories/warehouses are being

considered. Also get estimates of daily production, etc. for various locations (specifics, if possible or typical values). Compare to estimated need.

- Questions/Activities for Field Work
  - Attempt to verify that modular and other facilities are functioning and whether they are able to produce expected volumes of aflasafe.

Impact 8. The potential for cessation of USAID funding and the potential for toxigenic strains to return with potentially greater toxicity and/or a perception of safe crops that are actually not safe.

- Desk Study Approach
  - Some research has been performed regarding the frequency with which aflasafe must be re-applied (i.e., not necessarily every growing season). Are there any data regarding the nature of toxigenic strains that return that would indicate greater toxicity?
- Questions/Activities for Field Work
  - This may be primarily a desk exercise—we may not obtain a complete answer to this question. Ask field personnel (IITA) whether long-term monitoring for this potential issue is feasible and/or part of proposed activities.

Impact 9. Availability of robust sampling protocols for analytical methods to test for presence of aflatoxins in treated produce.

- Desk Study Approach
  - What sampling procedures are currently in place in the various regions of Africa to test for aflatoxin contamination?
  - Are these analytical procedures used by laboratories or as field-screening?
  - Is USAID interested in establishing uniform sampling and analytical procedures as part of this PEA, or are they willing to defer to IITA and/or local procedures in each country/region, or even laboratory level? The Food and Agriculture (FAO) branch of WHO has established procedures. Should these be a model?
  - Which aflatoxin compounds are subject to national health standards and/or are included in analytical methods? Aflatoxin B_1 and B_2, and/or G_1 and G_2?
  - What volumes of maize are subject to sampling and analysis (small bags, small bins, large bins, railroad cars, silos, etc.)? This may vary from country to country, but bushels collected for sampling and analysis may dictate sampling protocols.
- Questions/Activities for Field Work
  - Obtain copies of any sampling protocols and analytical methods (field screening or laboratory) used for assessing aflasafe efficacy and viability of crops.

Impact 10. The scope of introducing aflasafe to the EAC and using the work in the EAC as a model for use of aflasafe across sub-Saharan Africa is such that issues may arise regarding consistency in proper procedural and implementation processes. Thus, a PEA is needed.

- Desk Study Approach
  - Compile country-specific requirements for registration of pesticides and any requirements that might be unique to aflasafe.
- Questions/Activities for Field Work
  - Supplement desk study information with interviews with regulatory personnel. For example, Charity Mutegi of IITA has been working with Pest Control Products Board (PCPB) of Kenya to register aflasafe.

Additional Environmental and Social Impacts Raised for Consideration Following Scoping

Impact 11. What effects might use of aflasafe have on termite mounds? Termites and certain fungi have a symbiotic relationship and there is concern that aflasafe may out-compete other species of fungi, such as those involved with termite populations.

- Desk Study Approach
  - Evaluate published literature (if any) on effects of *A. flavus* on termites or other fungi on which termites are dependent.
- Questions/Activities for Field Work
  - Agronomist to observe termite mounds near aflasafe-treated fields.
  - Can samples of fungi on termite mounds be collected and speciated?

Impact 12. What are the processes in place regarding marketing, certification, and/or distribution of products coming from aflasafe-treated fields?

- Questions/Activities for Field Work
  - How will products coming from aflasafe-treated fields be packaged or marketed? What are the storage considerations?
  - What will be the shelf-life/expiration for these products? Will it change relative to products with limited or no exposure to *A. flavus?*
  - Will there be limitations in ability to discern 'safe' and 'unsafe' products at market? If so, will this roll-out lead to a false sense of security among consumers?

TASK 3. DETERMINE KEY STAKEHOLDERS TO ENGAGE DURING FIELD MISSIONS THROUGH DISCUSSION WITH EACH OF USAID/EAST AFRICA, USAID/KENYA, USAID/TANZANIA, USAID/RWANDA, AND USAID/UGANDA. STATUS: IN PROCESS

While engagement with bilateral missions and the USAID/East Africa mission will continue, to this point the following key resources and stakeholders have been identified for contact:

International Institute of Tropical Agriculture (IITA)

- [redacted]
  Plant Pathologist
  IITA
- [redacted]
  Kenya Country Coordinator, aflasafe Project
  IITA

USDA/Research Support and USAID Implementing Partners

- [redacted]
  Adjunct Professor, Research Plant Pathologist
  Agricultural Research Service, USDA, School of Plant Sciences, University of Arizona, Tucson
- [redacted]
  Manager, Biopesticide and Organic Support Program
  IR-4 Project, Rutgers University
- [redacted]
  USDA-FAS
- [redacted]
  FDA Mycotoxin Laboratory
- [redacted]
  University of Arizona
- [redacted]
  Texas A&M extension

- [redacted]
  AATF
- **Kenya Agricultural Research Institute (KARI)**
  University of Nairobi
- [redacted]
  Aflastop
- [redacted]
  Meridian
- [redacted]
  National Peanut Research Laboratory

Regulatory Entities/Host-country Plant Health and Pesticide Control Institutions

- **Kenya Pest Control Products Board (PCPB)** (http://www.pcpb.or.ke/)
- **Kenya National Environmental Management Authority (NEMA)** (http://www.nema.go.ke/)
- **Kenya Ministry of Health** (http://www.health.go.ke/)
- **Kenya Plant Health Inspectorate Service (KEPHIS)** (http://www.kephis.org/)
- **Kenya Ministry of Agriculture, Livestock and Fisheries, Department of Veterinary Services** (http://www.livestock.go.ke/)
- **Tanzania Pesticide Research Institute** (http://www.tpri.or.tz/)
- **Rwanda Ministry of Agriculture and Animal Resources** (http://www.minagri.gov.rw/index.php?id=613)
- **African Agricultural Technology Foundation**
- **United States Environmental Protection Agency**

TASK 4. FINALIZE FIELD WORK PLANNING, LOGISTICS, AND ARRANGEMENT OF STAKEHOLDER MEETINGS

STATUS: PENDING

TASK 5. CONDUCT FIELD MISSION, PROVIDE "MID-BRIEF", AND SOLICIT FEEDBACK FROM USAID/EAST AFRICA REGARDING PROPOSED ENVIRONMENTAL MANAGEMENT APPROACHES.

STATUS: PENDING

In order to maximize time and resources, GEMS envisions splitting the larger PEA team into two field teams, each focusing on multiple countries. The two field teams will convene in Nairobi toward conclusion of the field work for a formal field work out-brief with USAID/East Africa and other stakeholders.

- Team A will focus on Rwanda and Kenya, with approximately one week in each country.
- Team B will divide field work between Tanzania, Uganda, and Burundi, with a primary focus on Tanzania. Team B will also overlap with Team A in Nairobi for the mission out-brief.

Itineraries for both field teams are provided below. General objectives of the PEA field work are to:

1. Meet with host-country stakeholders promoting the development/manufacture, field testing and distribution of aflasafe, including USAID, IITA, NGOs, farming associations, academic research entities, etc.
2. Meet with host-country government and regulatory institutions to understand the pesticide product registration process and collaboration between USAID and host countries.
3. Visit and observe lab facilities to understand and evaluate capacity to research and contain harmful strains of *A. flavus*; quantify Standard Operating Procedures (SOPs), where applicable.
4. Visit aflasafe manufacturing and distribution facilities, as possible, to assess standards of production and dissemination.

5. Visit farms and grain storehouses to assess the use of GMPs.

FIELD TEAM A ITINERARY (RWANDA & KENYA)*

*** RWANDA FIELD WORK WAS POSTPONED AT THE REQUEST OF USAID; FIELD TEAM A WILL COMMENCE PEA FIELD WORK IN KENYA WEEK OF 9 JUNE, 2014.**

Day	Dates	Location	Field Team Activity
~~0~~	~~Sunday 01/Monday 02 June~~	~~Kigali~~	▪ ~~Field team arrives Kigali~~
~~1-2~~	~~Tuesday & Wednesday, 03 – 04 June~~	~~Kigali~~	▪ ~~In-brief with USAID/Rwanda~~ ▪ ~~Stakeholder interviews/visits: government representatives; laboratories; IITA~~
~~3~~	~~Thursday 05 June~~	~~Kigali & Other~~	▪ ~~Morning: depart Kigali for field site visit #1 (location TBD)~~ ▪ ~~Afternoon: local stakeholder interviews/consultations~~
~~4~~	~~Friday 06 June~~	~~Kigali & Other~~	▪ ~~Morning: local stakeholder interviews/consultations (cont.)~~ ▪ ~~Afternoon: depart for field site visit #2 (location TBD)~~
~~5~~	~~Saturday 07 June~~	~~Kigali & Other~~	▪ ~~Full day: local stakeholder interviews/consultations~~
~~6~~	~~Sunday 08 June~~	~~Kigali & Nairobi~~	▪ ~~Morning: return to Kigali~~ ▪ ~~Mid-day: depart Kigali for Nairobi~~ ▪ ~~Afternoon: arrive Nairobi and settle in~~
7	Monday 09 June	Nairobi	▪ In-brief with USAID/East Africa & USAID/Kenya ▪ Stakeholder interviews/visits: government representatives; laboratories; IITA
8	Tuesday 10 June	Nairobi & Other	▪ Morning: stakeholder interviews/visits (cont.) ▪ Afternoon: depart Nairobi for field site visit #3 (location TBD) ▪ Afternoon: local stakeholder interviews/consultations
9	Wednesday 11 June	Nairobi & Other	▪ Morning: local stakeholder interviews/consultations (cont.) ▪ Afternoon: depart for field site visit #4 (location TBD)
10	Thursday 12 June	Nairobi & Other	▪ Morning: local stakeholder interviews/consultations ▪ Afternoon: return to Nairobi
11	Friday 13 June	Nairobi	▪ Morning: "Mid-Brief" report out to USAID/East Africa on field work findings to date ▪ Afternoon: additional stakeholder meetings ▪ Late evening: depart Nairobi—conclude Field Team A mission

FIELD TEAM B ITINERARY (TANZANIA, KENYA, UGANDA, & BURUNDI)

Day	Dates	Location	EA Team Activity
0	Wednesday 04 June	Dar es Salaam (Dar)	▪ Field team arrives Dar
1	Thursday 05 June	Dar	▪ In-brief with USAID/Tanzania ▪ Stakeholder interviews/visits: government representatives; laboratories; IITA
2	Friday 06 June	Dar & Other	▪ Morning: stakeholder interviews/visits (cont.) ▪ Afternoon: depart Dar for field site visit #1 (location TBD)
3	Saturday 07 June	Dar & Other	▪ Full day: local stakeholder interviews/consultations
4	Sunday 08 June	Dar & Other	▪ Morning: local stakeholder interviews/consultations (cont.) ▪ Afternoon: desk work/planning for subsequent field visits
5	Monday 09 June	Dar & Other	▪ Morning: depart for field site visit #2 (location TBD) ▪ Afternoon: local stakeholder interviews/consultations
6	Tuesday 10 June	Dar & Other	▪ Full day: local stakeholder interviews/consultations (cont.)
7	Wednesday 11 June	Dar & Other	▪ Morning: return to Dar ▪ Afternoon: stakeholder interviews/visits

Day	Dates	Location	EA Team Activity
8	Thursday 12 June	Dar & Nairobi	▪ Morning: stakeholder interviews/visits (cont.) ▪ Afternoon: depart Dar for Nairobi
9	Friday 13 June	Nairobi	▪ Morning: "Mid-Brief" report out to USAID/East Africa on field work findings to date ▪ Afternoon: additional stakeholder meetings
10	Saturday 14 June	Nairobi	▪ Full day: additional stakeholder meetings (cont.)
11	Sunday 15 June	Nairobi & Kampala/ Bujumbura	▪ Morning: depart Nairobi for Kampala/Bujumbura ▪ Afternoon: arrive and settle in in Kampala/Bujumbura
12	Monday 16 June	Kampala/ Bujumbura	▪ Morning: in-brief with USAID/Uganda (Uganda) ▪ Afternoon: stakeholder interviews/visits: government representatives; laboratories; IITA (Uganda)
			▪ Full day: stakeholder interviews/visits: government representatives; laboratories; IITA (Burundi)
13	Tuesday 17 June	Kampala/ Bujumbura & Other	▪ Morning: depart for field site visit #3 (Uganda location TBD) ▪ Afternoon: stakeholder interviews/visits
			▪ Morning: depart for field site visit #4 (Burundi location TBD) ▪ Afternoon: stakeholder interviews/visits
14	Wednesday 18 June	Kampala/ Bujumbura & Other	▪ Morning: stakeholder interviews/visits site visit #3 (cont.) (Uganda) ▪ Afternoon: return to Kampala ▪ Evening: conclude Field Team B mission
			▪ Morning: stakeholder interviews/visits site visit #4 (cont.) (Burundi) ▪ Afternoon: return to Bujumbura ▪ Late evening: depart Bujumbura—conclude Field Team B mission

Task 6. Prepare draft core PEA, East Africa PEA Amendment, and Environmental Mitigation and Monitoring Framework
STATUS: PENDING

The programmatic nature of the proposed aflasafe activities, both in the EAC and throughout Sub-Saharan Africa, necessitates a framework approach to environmentally sound management. As such, this PEA proposes to introduce and utilize an environmental mitigation and monitoring framework which will govern subsequent environmental mitigation and monitoring plans used to safeguard aflasafe activities against foreseeable and preventable or mitigable adverse environmental impacts.

Initial Draft Outline for Core PEA

1. Introduction
2. Project Description
3. Baseline Data / Affected Environment
4. Policy, Legal, Regulatory and Institutional Setting
5. Environmental and Social Impacts (or Consequences)
6. Analysis of Alternatives
7. Environmental and Social Mitigation Plan
8. Environmental and Social Management and Training
9. Environmental and Social Monitoring Plan
10. Public Consultation

APPENDIXES

A. List of Preparers

B. Sources (Documents, Persons and Organizations)

C. Scoping Statement

D. Technical appendices, as needed

Task 7. Receive USAID comments from draft review; address comments

Task 8. Submit Final Draft of core PEA and East Africa PEA Amendment

Task 9. Receive USAID comments on Final Draft documents

Task 10. Submit Final core PEA and East Africa PEA Amendment

STAFFING

USAID

Technical supervision for the aflasafe PEA will be provided by:

Mary Onsongo
Program Management Specialist
Agricultural Markets and Value Chains
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GEMS PEA TEAM

The GEMS PEA team will consist of six core Environmental Impact Assessment (EIA) and technical/scientific staff. This core team will be supported by Cadmus home office-based administrative and program management personnel. The proposed core team members are:

- [redacted]**, Team Leader**—Given the profile and strong technical orientation of the full PEA team, the Team Leader is expected to serve primarily as coordinator and integrator, ensuring the team's overall expertise and analysis align with the PEA workplan, reflect sound EIA methodology, and conform to USAID Environmental Procedures. The Team Leader will also serve as the team's primary point of contact with USAID and oversee all aspects of PEA planning, preparation and submission, including coordination of all field work. The Team Leader will have at least 10 years of EIA and international development experience, including significant field work in Africa with an emphasis on natural resource management, agricultural production and/or food security.

- [redacted]**, Risk Assessor** —The manufacture, field testing and distribution of aflasafe requires thorough evaluation of the potential toxicological risks to humans, plants and animals. The Risk Assessor will provide data and analysis to inform assessment of the environmental issues of significant potential concern identified through the scoping process, as well as any other issues that arise during preparation of the PEA.

- [redacted]**, Field Agronomist** —aflasafe is intended for use as an agricultural input. The PEA must assess this product in the context of farming systems in East Africa. This includes understanding the ecological, cultural and economic implications of aflasafe use in food production networks that also underpin development at the household, regional and often national levels.

- [redacted]**, Food Safety and Production Specialist** —Widespread aflasafe distribution will depend on production facilities that can generate sufficient amounts of atoxigenic *A. flavus* to specification. The PEA will need to consider the viability and safety of manufacturing facilities at all scales. Output from these manufacturing facilities will have direct bearing on food safety and human health among populations consuming aflasafe-treated crops.

- [redacted]**, Plant Geneticist** —The isolation and selection of *A. flavus* strains suitable for regional aflasafe products requires sophisticated laboratory procedures and analysis. The PEA will need to evaluate these processes as scientific bases of selection and lab-based determinations will have significant impact on aflasafe use in the field.

- [redacted]**, EIA Specialist**—The EIA Specialist will help facilitate overall PEA team collaboration, working with individual technical specialists to identify and fully explore common elements of analysis, which may entail additional research and/or evaluation. The EIA Specialist will also support the PEA field work component, potentially organizing and leading one of the field contingents.

In addition to this core team, a **US review team** is available for technical assistance on an as-needed basis and will provide QA/QC. The team may include:

- [redacted]. Mr. Fisher serves as the GEMS project-wide EIA Specialist. An outgoing board member of the International Association for Impact Assessment, he has more than 30 years of experience in natural resource policy, planning and management.
- [redacted]. Dr. Stoughton is the GEMS II project Team Leader and an expert in the use of USAID Environmental Procedures and is the lead author of the USAID *Environmental Procedures Training Manual*, co-author of the *Mission Environmental Officers Handbook,* and is the key editor of USAID's *Environmental Guidelines for Small-Scale Activities in Africa.*

ATTACHMENT D: AFLASAFE ENVIRONMENTAL MITIGATION AND MONITORING PLAN (EMMP) TEMPLATES

These template EMMPs can be easily adapted for implementation at each of the various stages of aflasafe manufacture and use. The templates correspond with the aflasafe lifecycle phases described in the Environmental Mitigation and Monitoring Framework (PEA Section 7). In preparing the EMMP(s), USAID and/or Implementing Partners should adapt or respond to the highlighted text or instructions in the template(s) according to project-specific circumstances or requirements. Once the project-specific addition is made to the EMMP template, the preparer should delete the highlighted text or instructions.

PHASE 2: AWARENESS RAISING AND DEMAND CREATION

Environmental/Social Impacts at Phase	Environmental Mitigation Measures	Timing & Frequency of Environmental Mitigation Measures	Roles & Responsibilities	Monitoring Measures
Unrealistic expectations about aflasafe leading to unsafe consumption or dissatisfied users of the product	Disseminate pamphlets, provide aflasafe demonstrations, and/or organize community meetings, etc., to raise awareness that aflasafe is not a quick-fix solution, but rather a tool within a set of control resources for aflatoxins. Establish realistic expectations about the efficacy of aflasafe and the parameters for use in order to maximize beneficial results. Ensure that policy makers, beneficiaries, smallholder farmers, and all stakeholders along the agricultural value	***Note to preparer regarding completion of the EMMP template**: Awareness-raising should be conducted at project outset, and persist throughout life-of-project. (e.g., weekly or quarterly)*	***Note to preparer regarding completion of the EMMP template:** Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA, Awareness-raising will be a joint responsibility between the IP and relevant government agencies. Private-sector actors along the value chain should also be consulted.*	***Note to preparer regarding completion of the EMMP template:** The IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.*

	chain are recipient to and cognizant of awareness building efforts.			
Insufficient awareness or demand leading to lack of market differentiation for treated and/or safer products, undermining trust among consumers in aflasafe as a viable bio-control approach.	Direct or indirect support to development of, certification/labelling/branding processes and requirements in line with increases in product popularity.	***Note to preparer regarding completion of the EMMP template:*** ***The timeline for development and formalization of certification/labeling/ branding processes will vary by country. It is unlikely that such processes will be developed sooner than 2-3 years following introduction of aflasafe, though in reality, reliable process development may take much longer.***	***Note to preparer regarding completion of the EMMP template:*** ***Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA, the IP must ensure that aflasafe is understood as part of a broader suite of options for the control of aflatoxins.***	***Note to preparer regarding completion of the EMMP template:*** ***The IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.***
Note to preparer regarding completion of the EMMP template: ***The IP should populate these rows with additional context-specific impacts, mitigation measures, roles & responsibilities, and monitoring measures (as applicable).***				
Note to preparer regarding completion of the EMMP template: ***The IP should populate these rows with additional context-specific impacts, mitigation measures, roles & responsibilities, and monitoring measures (as applicable).***				

PHASE 3: REGISTRATION OF AFLASAFE

Environmental/Social Impacts at Phase	Environmental Mitigation Measures	Timing & Frequency of Environmental Mitigation Measures	Roles & Responsibilities	Monitoring Measures
No potentially significant adverse environmental or social impacts pertaining to the manufacture or use of aflasafe are anticipated at this lifecycle phase.	Adhere to the host-country's (and/or any governing regional) bio-pesticide registration processes to ensure registration of a safe product in a manner that has little to no adverse environmental impact.	***Note to preparer regarding completion of the EMMP template:*** ***The specific registration process and timing will be subject to host-country and regional registration procedures (including fees and periodic reregistration, where required).***	***Note to preparer regarding completion of the EMMP template:*** ***Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA, the IP will support (as appropriate) in-country field testing efforts and meet necessary registration and permitting fee requirements.***	***Note to preparer regarding completion of the EMMP template:*** ***The IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.***
Note to preparer regarding completion of the EMMP template: ***The IP should populate these rows with additional context-specific impacts, mitigation measures, roles & responsibilities, and monitoring measures (as applicable).***				
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applicable).				

PHASE 4: ESTABLISHMENT OF MANUFACTURING

Environmental/Social Impacts at Phase	Environmental Mitigation Measures	Timing & Frequency of Environmental Mitigation Measures	Roles & Responsibilities	Monitoring measures
Improper site selection or insufficient controls at the facility leading to air-borne fungal exposure by local immunocompromised populations.	Ensure that manufacturing facilities comply with basic worker safety and environmental controls, including air, handling equipment, and wastewater and solid waste management. These requirements must be met during pre-construction planning.	During planning and design of manufacturing facilities, air, water, and solid waste quality management infrastructure must be accounted for and included in manufacturing facility specifications. This is a one-time, up-front requirement.	***Note to preparer regarding completion of the EMMP template:* Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA, the IP, in coordination with AOR/COR and MEO or REO/A is responsible for ensuring sound design and construction of the manufacturing facility.**	***Note to preparer regarding completion of the EMMP template:* The IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.**
Poor siting or construction practices lead to undue environmental impacts (e.g., siltation of area water bodies, soil erosion or degradation).	The construction of manufacturing facilities must comply with all applicable host-country review and certification/approval requirements. Where host-country permitting or environmental assessment is not required, ensure that all candidate sites for manufacturing facility are screened for any potential	***Note to preparer regarding completion of the EMMP template:* Site screening must be conducted for candidate sites prior to any final siting decisions. Applicable host-country permitting requirements for screening timing and frequency should be clarified in this EMMP.**	***Note to preparer regarding completion of the EMMP template:* Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA, the IP will be responsible for preparation of all host-country documentation. If host-country permitting or environmental assessment is not required, the IP is responsible for ensuring**	***Note to preparer regarding completion of the EMMP template:* The IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.**

	risks to the local community or environment. ***<u>Note to preparer regarding completion of the EMMP template:</u> Refer to the <u>USAID Sector Environmental Guideline on Small-scale Construction</u> for more information on mitigating negative environmental impacts from construction***.		***that candidate sites are screened for potential risks to the local community or environment.***	
Poor site selection can make post-production distribution to target beneficiaries onerous, inefficient, or otherwise challenged.	Ensure the selected site for manufacturing facilities accounts for proximity and/or access to target beneficiaries	***<u>Note to preparer regarding completion of the EMMP template:</u> Site screening must be conducted for candidate sites prior to any final siting decisions. Applicable host-country permitting requirements for screening timing and frequency should be clarified in this EMMP.***	***<u>Note to preparer regarding completion of the EMMP template:</u> Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA, the IP is responsible for ensuring that the site selection accounts for target beneficiaries.***	***<u>Note to preparer regarding completion of the EMMP template:</u> The IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.***
<u>Note to preparer regarding completion of the EMMP template:</u> The IP should populate these rows with additional context-specific impacts, mitigation measures, roles & responsibilities, and monitoring measures (as applicable).				

Note to preparer regarding completion of the EMMP template: ***The IP should populate these rows with additional context-specific impacts, mitigation measures, roles & responsibilities, and monitoring measures (as applicable).***				

PHASE 5: MANUFACTURING PROCESSES AND AFLASAFE PRODUCTION

Environmental/Social Impacts at Phase	Environmental Mitigation Measures	Timing & Frequency of Environmental Mitigation Measures	Roles & Responsibilities	Monitoring measures
Production of low-quality product through improper adherence to manufacturing processes, limiting effectiveness upon application.	Ensure that QA/QC mechanisms are instituted as part of the manufacturing process via preparation and maintenance of Standard Operating Procedures (SOPs) to ensure the availability of aflasafe that is effective and performs to expectations. SOPs must address all operational aspects of the facility, including, but not limited to, maintenance and security procedures, scheduling, and technical procedural steps to be taken during the production of aflasafe. Each batch of aflasafe should maintain tracking	***Note to preparer regarding completion of the EMMP template:*** ***The manufacturing facility is to be inspected routinely (e.g., weekly or monthly) throughout facility operation to assure that machinery and production equipment is operating as specified and that SOPs are being adhered to***	***Note to preparer regarding completion of the EMMP template:*** ***Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA, the IP is responsible for regular inspections of the manufacturing facility and for preparation of the SOPs. The AOR/COR and REO/A or MEO must approve all SOPs.***	***Note to preparer regarding completion of the EMMP template:*** ***The IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.***

	systems for raw materials used (including source, cost, and Lot Numbers, where applicable), process steps implemented, and production volumes. Manufacturing facilities should have an on-site laboratory or an effective system to evaluate the quality of the aflasafe upon production, prior to packaging and distribution.			
Improper packaging increasing risk of product contamination.	Ensure that basic, low-cost facility and process controls are in place to contain aflasafe and its active ingredients, preventing dispersal to or contamination of the local environment. Establish a system to prevent potential adverse impacts on nearby sensitive or immunocompromised populations.	Each batch of aflasafe produced should be verified at a sufficiently equipped laboratory for quality.	***Note to preparer regarding completion of the EMMP template:* Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA, the IP is responsible for ensuring manufacturing facilities have the necessary equipment and perform quality inspections of all packaging.**	***Note to preparer regarding completion of the EMMP template:* The IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.**
***Note to preparer regarding completion of the EMMP template:* The IP should populate these rows with additional context-specific impacts, mitigation measures, roles & responsibilities, and monitoring measures (as applicable).**				

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PHASE 6: POST-PRODUCTION STORAGE AND DISTRIBUTION

Environmental/Social Impacts at Phase	Environmental Mitigation Measures	Timing & Frequency of Environmental Mitigation Measures	Roles & Responsibilities	Monitoring measures
Unreliable agro-suppliers could contaminate the product or distribute artificial or fraudulent proxies.	Establish protocols to channel finished product through reliable and trustworthy input and agro-supply dealer networks and made available to consumers at a competitive price.	***Note to preparer regarding completion of the EMMP template:* Oversight of post-production storage and distribution will be necessary throughout life-of-project. This will be most effectively done via visits to agro-retailers or agricultural extension agents that are predominant drivers of aflasafe sale and/or distribution. Such visits should occur quarterly during the first year of production, and at least semi-annually thereafter.**	***Note to preparer regarding completion of the EMMP template:* Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA, the IP, MEO or REO/A, and AOR/COR should all be active participants in site visits to agro-retailers or extension agents distributing aflasafe.**	***Note to preparer regarding completion of the EMMP template:* The IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.**
Disaggregated value chains, or weakened infrastructure, could lead to inefficient or ineffective distribution channels	Leverage existing distribution channels, such as Ministry of Agriculture Extension Services or other agricultural support mechanisms where possible to reduce costs and potential inefficiencies in distribution.			***Note to preparer regarding completion of the EMMP template:* The IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring**

				measures to ensure EMMP implementation and reporting.
Note to preparer regarding completion of the EMMP template: ***The IP should populate these rows with additional context-specific impacts, mitigation measures, roles & responsibilities, and monitoring measures (as applicable).***				
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PHASE 7: USE OF AFLASAFE

ENVIRONMENTAL/SOCIAL IMPACTS AT PHASE	ENVIRONMENTAL MITIGATION MEASURES	TIMING & FREQUENCY OF ENVIRONMENTAL MITIGATION MEASURES	ROLES & RESPONSIBILITIES	MONITORING MEASURES
Improper application technique could reduce, or eliminate, efficacy of aflasafe (e.g., applying the product too late).	Carry out trainings and/or demonstrations on proper application, handling, storage, and disposal of aflasafe, and incorporate these	***Note to preparer regarding completion of the EMMP template:*** ***Consistent with Section 8 of the PEA, the IP will evaluate the need for***	***Note to preparer regarding completion of the EMMP template:*** ***Consistent with the Environmental Mitigation and Monitoring***	***Note to preparer regarding completion of the EMMP template:*** ***The IP should work with the AOR/COR and MEO (or in non-***

	trainings/demonstrations into aflasafe manufacture and use activities. Ensure Ministry of Agriculture Extension Services, or like agricultural support mechanisms, are beneficiaries of awareness-raising and capacity building efforts on aflatoxins and aflasafe. Utilize a "training the trainers" program to empower downstream training on proper use of aflasafe.	***awareness building and develop a training and capacity building program that details the frequency of demonstrations.***	***Framework in Section 7 of the PEA, the IP will be responsible for conducting initial evaluations of the need for awareness raising and capacity building and for development of a training and capacity building program.*** ***The REO/A, MEO, or both, will be responsible for review and approval of the training and capacity building curricula.***	***presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.***
Improper storage could expose the product to contamination or early expiration.	Carry out trainings and/or demonstrations on proper application, handling, storage, and disposal of aflasafe for aflasafe manufacture and use activities. Ensure that inventory management systems are in place to help identify storage issues and track potential expiration of stored products. As products near expiration, if they are unlikely to be used at current location, re-distribution should be explored (through coordination with AOR/COR and potentially host-government authorities)	***<u>Note to preparer regarding completion of the EMMP template:</u> Inventory management systems should be integrated upon receipt of product at all appropriate stops along the value chain. Inventory management should be an ongoing priority, with weekly or, at minimum, monthly reviews of stocked aflasafe.***	***<u>Note to preparer regarding completion of the EMMP template:</u> Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA, the REO/A, MEO, and AOR/COR should review and support IP development and integration of inventory management systems across the value chain.***	***<u>Note to preparer regarding completion of the EMMP template:</u> The IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.***

***Note to preparer regarding completion of the EMMP template:* The IP should populate these rows with additional context-specific impacts, mitigation measures, roles & responsibilities, and monitoring measures as applicable.**				
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PHASE 8: FOOD SAFETY SURVEILLANCE

Environmental/Social Impacts at Phase	Environmental Mitigation Measures	Timing & Frequency of Environmental Mitigation Measures	Roles & Responsibilities	Monitoring measures
The misperception of unsafe crops as safe may present adverse impacts that would not otherwise be faced by impacted populations, particularly more vulnerable groups.	Because aflasafe has been shown to have an "area effect"[48] (meaning that it reduces levels of aflatoxins in the fields applied as well as adjacent and area fields), establish life-of-project monitoring that focuses on	Long-term monitoring efforts should entail, at minimum, seasonal sampling of both treated and untreated 'areas' to capture the efficacy and "area effect" of aflasafe use, if any. Sampling should begin prior to aflasafe production	*Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA*, the IP will be responsible for ensuring that seasonal sampling is conducted and the REO/A and/or MEOs and AOR/COR	*Consistent with section 7.3 of the PEA, the IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.*

[48] Personal communication with Peter Cotty, USDA; 10 July, 2014, via teleconference.

	comparisons of the levels of aflatoxins in treated areas versus those in untreated areas.	and use, and continue throughout life-of-project.	should participate in at least one sampling event each year.	
While unlikely, aflasafe could produce harmful secondary metabolites if there were a failure in strain identification and/or isolation.	Conduct epidemiological surveys to track prevalence of diseases linked to acute and chronic exposure to aflatoxins throughout life-of-project. In instances where epidemiological surveys are not practicable, raise awareness among Ministry of Health officials about potential health impacts associated with aflatoxins, and effective measures to track positive impacts stemming from reduction in aflatoxin levels over time.	***Note to preparer regarding completion of the EMMP template:* Conduct epidemiological surveys on an annual basis to track any potential trends indicating reduced exposure to aflatoxins.**	***Note to preparer regarding completion of the EMMP template:* Consistent with the Environmental Mitigation and Monitoring Framework in Section 7 of the PEA, the IP will be responsible for coordinating the implementation of epidemiological surveys. USAID AOR/COR should provide oversight for this process.**	***Note to preparer regarding completion of the EMMP template:* Consistent with section 7.3 of the PEA, the IP should work with the AOR/COR and MEO (or in non-presence countries, the REO/A) to establish appropriate monitoring measures to ensure EMMP implementation and reporting.**
***Note to preparer regarding completion of the EMMP template:* The IP should populate these rows with additional context-specific impacts, mitigation measures, roles & responsibilities, and monitoring measures as applicable.**				
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